Introduction—The Federal Transit Administration (FTA) published its revised rule on prohibited drug use and the prevention of alcohol misuse (49 CFR Part 655) on August 1, 2001. The FTA published the revised Implementation Guidelines for Drug and Alcohol Regulations in Mass Transit to provide a comprehensive overview of the regulations.

Since the Guidelines were published, there have been numerous amendments, interpretations, and clarifications to the Drug and Alcohol testing procedures and program requirements. This publication is being provided to update the Guidelines and inform your transit system of these changes. This update is the thirty-seventh in a series.

Final Rule Makes Validity Testing Mandatory

On June 25, 2008, the Department of Transportation (DOT) published a final rule that amends 49 CFR Part 40 to make specimen validity testing mandatory. The rule that was published in the Federal Register, Volume 73, pages 35961–35975, will become effective on August 25, 2008. The rule change provides direction to collectors, laboratories, medical review officers, and employers regarding adulterated, substituted, diluted, and invalid urine specimen drug test results.

The final rule (§40.89(b)) makes specimen validity testing mandatory for all DOT tests, including those conducted for employers covered by the Federal Transit Administration (FTA). Certified laboratories are required to follow the testing protocols for adulterated and invalid urine specimens that are established by the Department of Health and Human Services (HHS). The identity of adulterants tested for and the cutoff levels for adulterated or invalid test results are not included in the final rule as the DOT will follow the criteria established in the HHS Mandatory Guidelines.

In an effort to make it more difficult to adulterate or substitute specimens, the final rule requires that specimens be collected under direct observation any time there is a specific reason to believe that any employee may be attempting to thwart the rule or has sufficient reason to evade the testing process. The conduct of observed collections for return-to-duty and follow-up drug testing will no longer be optional, but will be a required component of these testing circumstances (§40.67). The manner in which the observed collections will be performed is also described (see article on Page 2).

The long list of potential test results reported by the laboratories and Medical Review Officers (MROs) was clarified and simplified. Additionally, the final rule expanded the definition of a test refusal to include an employee admission of adulteration or substitution during the MRO review process of an invalid test result.

In addition, the MRO review process following an invalid test result for test categories requiring negative test results (i.e., pre-employment) was modified to allow MROs to accept medical evaluations ruling out signs and symptoms of drug use when employees/applicants have medical reasons for providing invalid results (§40.160). This procedure is consistent with the medical review process allowed for pre-employment testing circumstances when an individual has insufficient volume due to a long term or permanent disability.

The final rule also requires laboratories to provide the DOT with semi-annual reports providing statistical summaries of their DOT testing results and provides a clarification of their blind specimen quality control measures to include adulterated and substituted specimens.

For additional information regarding the rule change and its implication for employees, employers, and service agents, please refer to the articles provided on the following pages.

Specimen Validity Testing Definitions

Adulterated A specimen is considered adulterated if it contains a substance that is not a normal constituent or contains an endogenous substance at a concentration that is not a normal physiological concentration.

Diluted Diluted specimens have creatinine and specific gravity values that are lower than expected for human urine. The HHS has determined that specimens with creatinine levels greater than or equal to 2.0 mg/dL but less than 20.0 mg/dL and have a specific gravity greater than or equal to 2.0 mg/dL but less than 5.0 mg/dL are required to be retested under direct observation.

Substituted Substituted specimens have creatinine and specific gravity values that are so diminished and/or divergent that they are not consistent with normal human urine. The HHS has determined that specimens with creatinine levels of less than 2.0 mg/dL are substituted.

Invalid An invalid specimen is one that contains an unidentified adulterant, contains an unidentified interfering substance, has an abnormal physical characteristic, or has an endogenous substance at an abnormal concentration that prevents the laboratory from completing testing or obtaining a valid drug test result.
Several changes to the DOT drug testing rules (49 CFR Part 40) will go into effect on August 25, 2008. The majority of the rule changes will directly impact urine specimen collectors, laboratories and Medical Review Officers (MROs). However, employers and employees covered by the regulations must also be aware of the changes to ensure compliance and to make corresponding modifications to policies and procedures. The guidance provided below constitutes an overview of regulatory changes and provides an example of how these issues can be addressed through policy modifications. Each employer, however, is instructed to review the regulation and make their own determination in consult with their legal counsel on how they can best incorporate the changes into their program.

**Testing Procedures:** Policies that include a discussion of the testing procedures should be modified to refer to the regulation as “49 CFR Part 40, as amended.” The discussion of the drug testing methodology that is used should indicate that validity testing is mandatory. Suggested language: “Specimen validity testing will be conducted on all urine specimens provided for testing under DOT authority. Specimen validity testing is the evaluation of the specimen to determine if it is consistent with normal human urine. The purpose of validity testing is to determine whether certain adulterants or foreign substances were added to the urine, if the urine was diluted, or if the specimen was substituted.”

**Observed Collections:** In order to guard against employee attempts to mask the testing process, the number of situations requiring direct observation has increased to include return-to-duty and follow-up testing with regards to employers that have second chance policies in place. The manner in which the observations will be conducted has also been re-defined to ensure that prosthetic devices may not be successfully and easily employed to mask illicit drug use. Suggested language: “Observed collections are required in the following circumstances:

- All return-to-duty tests;
- All follow-up tests;
- Anytime the employee is directed to provide another specimen because the temperature on the original specimen was out of the accepted temperature range of 90°F - 100°F;
- Anytime the employee is directed to provide another specimen because the original specimen appeared to have been tampered with;
- Anytime a collector observes materials brought to the collection site or the employee’s conduct clearly indicates an attempt to tamper with a specimen;
- Anytime the employee is directed to provide another specimen because the laboratory reported to the MRO that the original specimen was invalid and the MRO determined that there was not an adequate medical explanation for the result;
- Anytime the employee is directed to provide another specimen because the MRO determined that the original specimen was positive, adulterated or substituted, but had to be cancelled because the test of the split specimen could not be performed.

The employee who is being observed will be required to raise his or her shirt, blouse, or dress/skirt, as appropriate, above the waist; and lower clothing and underpants to show the collector, by turning around that they do not have a prosthetic device.”

**Split Specimen Testing:** Employees that have a verified positive drug test result or a test refusal due to adulteration or substitution may request a test of their split specimen. However, there is no split specimen testing for an invalid result. Suggested language: “Employees do not have access to a test of their split specimen following an invalid result.”

**Negative Dilute:** The regulation was clarified regarding the number of times an employee can be required to take an additional test following a negative dilute test result. If an employer has a policy that requires an employee to take an additional test if he/she has a negative dilute result, the employer should consider adding the following language to their policy: “Following a negative dilute the employee will be required to undergo another test. Should this second test result in a negative dilute result, the test will be considered a negative and no additional testing will be required unless directed to do so by the MRO.”
Test Refusals: Additional behaviors have been added to the list of behaviors that constitutes a test refusal. Your policy must include all behaviors that constitute a test refusal. Numbers 9, 10, and 11 in the list below were added under Part 40.191(a) in the recent amendment and will need to be specifically added to your testing policy. “The following behaviors constitute a test refusal:

1. Failure to appear for any test (except for pre-employment) within a reasonable time, as determined by the employer;
2. Failure to remain at the testing site until the testing process is complete;
3. Failure to provide a urine specimen for any required drug test;
4. Failure to permit the observation or monitoring of the specimen collection when required to do so;
5. Failure to provide a sufficient amount of urine when directed and there is no adequate medical explanation for the failure;
6. Failure to take a second test when directed to do so by the employer or collector;
7. Failure to undergo a medical examination when directed to do so by the MRO or employer;
8. Failure to cooperate with any part of the testing process (e.g., refuse to empty pockets when directed by the collector, behave in a confrontational way that disrupts the collection process, fail to wash hands after being directed to do so by the collector);
9. Failure to follow the observer’s instructions during an observed collection including instructions to raise your clothing above the waist, lower clothing and underpants, and to turn around to permit the observer to determine if you have any type of prosthetic or other device that could be used to interfere with the collection process;
10. Possess or wear a prosthetic or other device that could be used to interfere with the collection process; and
11. Admit to the collector or MRO that you adulterated or substituted the specimen.”

There are currently forty-two (42) laboratories that meet the minimum standards and are certified by the Department of Health and Human Services (HHS) to perform urine drug testing for Federal agencies. The list is updated every month and published in the Federal Register during the first week of each month. The list can also be obtained from the ODAPC website.

Beginning August 25, 2008, each of these laboratories will be required to perform mandatory validity testing on all DOT drug tests. The laboratories must use the cutoff concentrations for the initial and confirmation adulterant testing as required by the HHS Mandatory Guidelines and must provide the numerical value that supports the adulterated result. Similarly, the laboratories must use the invalid test result criteria for the initial and confirmation testing as required by the HHS Mandatory Guidelines. The laboratory must report why the test result is invalid and must provide the numerical value that supports the invalid result. The laboratory must also discuss with the MRO whether sending a specimen to a second HHS certified laboratory would be useful in distinguishing an invalid specimen as either positive or adulterated.

Laboratories will report the results to the MRO in the following manner:

- Negative Results
  - Negative
  - Negative-dilute with numeric values for creatinine and specific gravity
- Non-negative Results
  - Positive with drug(s)/metabolite noted
  - Positive-dilute with drug(s)/metabolite noted and numerical valued for creatinine and specific gravity
  - Adulterated with adulterant(s) noted with confirmatory test values if appropriate and remarks
  - Substituted with confirmatory test values for creatinine and specific gravity
  - Invalid with remarks and actual values for pH results
- Rejected for Testing
  - Rejected for Testing with remarks
Medical Review Officers are the gatekeepers of the DOT drug testing program and are responsible for the accuracy and integrity of the drug testing process. As such, they are the last line of defense against employees who attempt to thwart the process by adulterating or substituting their specimen. In this vein, the modifications to Part 40 have increased the MRO’s responsibility and clarified the MRO-verified drug test results.

The regulation provided additional instruction to the MRO regarding what to do in the following instances:

- A no contact invalid test result—verify as cancelled and require recollect under direct observation;
- A second negative dilute result when the re-collection was not directly observed as required—require re-collect under direct observation;
- An invalid result is reported by the lab—the MRO must discuss the result with the certifying scientist to determine if the primary specimen should be tested at another HHS certified laboratory;
- A recollect following an invalid test result is also invalid for the same acceptable reason—verify as cancelled unless a negative test is required (i.e., pre-employment, return-to-duty, follow-up), then follow the procedures outlined in §40.160 to determine if there is clinical evidence that the individual is an illicit drug user. If no evidence is found, report the result as negative. If evidence of illicit drug use is found, the test is cancelled;
- A second invalid result when the re-collection was not directly observed as required—require re-collect under direct observation; and
- An employee requests a test of a split specimen following an invalid test result—split specimen testing for an invalid result is not permitted.

The regulation instructs MROs to report verified drug test results as negative; cancelled; positive; and/or refusal to test because of adulteration or substitution (§40.129). The regulation provides additional instruction when the MRO verifies multiple results for the same testing event (§40.162) and under various split specimen result scenarios (§40.187).
**QUESTIONS & ANSWERS**

Q  How can I make sure that my collection site is aware of the new regulations?

A  Service agents are required to follow the procedures defined in 49 CFR Part 40, as amended, if they are going to conduct tests for DOT-covered employers. However, the employer remains accountable for compliance. Failure of the service agent to implement any aspect of the regulation, results in the noncompliance of the employer. A best practice for employers following any regulatory change is to contact the facility manager. Discuss the changes and the manner in which the collectors will be informed or re-trained on the new procedures. The employer can provide copies of the revised Urine Specimen Collection Guidelines or other resources that would be useful to the service agent. The employer may also conduct a mock collection to see that the new procedures have been incorporated.

Q  My collection site only has female collectors, but most of my employees are male. If one of my male employees has to have an observed collection, how will they do it?

A  Section 40.67(g) states that the collector must ensure that the observer is the same gender as the employee. The collector must never permit an opposite gender person to act as the observer, even if they are a physician, nurse, or other medical practitioner. The observer can be a different person from the collector and need not be a qualified collector. If the observer is someone other than the collector, the collector is responsible for verbally instructing that person to follow the procedures defined in Part 40 and the Urine Specimen Collection Guidelines. As the employer, you should contact your collection site manager to determine the procedures that are in place to ensure that the site has access to male and female observers during all times that collections are performed. ODAPC also permits a same gender supervisor from the employer to act as the observer if no other alternate method/personnel is available at the collection site.

**COMMON AUDIT FINDINGS**

**Post Accident Test Decision Documentation**

Most transit systems have a procedure in place to document the decision to test following an accident that meets the minimum FTA criteria, however, few document the decision not to test. Both are required. Section 655.44(d) states that “the decision not to administer a drug and/or alcohol test under this section shall be based on the employer’s determination, using the best available information at the time of the determination that the employee’s performance could not have contributed to the accident. Such a decision must be documented in detail, including the decision-making process used to reach the decision not to test.”

An industry best practice is to create a standard form that documents the decision to test or not to test and incorporate the form into the employer’s standard accident/incident reporting procedure. Sample post-accident test decision forms are provided in Appendix B of the Best Practices Manual: FTA Drug and Alcohol Testing Program that can be downloaded from FTA’s website at [http://transit-safety.volpe.dot.gov](http://transit-safety.volpe.dot.gov). Click “Drug and Alcohol” and then click “Drug and Alcohol Publications.”

**Term “Disabling Damage” Misunderstood**

One of the criteria used to determine if a FTA post-accident test is required is whether or not one or more of the vehicles involved in the accident received disabling damage. Most people too narrowly define disabling damage to mean the vehicle is towed from the scene. In actuality, the definition of disabling damage is broader. Section 655.4 defines disabling damage as “damage that precludes departure of a motor vehicle from the scene of the accident in its usual manner in daylight after simple repair; or damage to any vehicle that could have been operated but which would have further damaged the vehicle if so operated. Disabling damage does not include damage that could be remedied temporarily at the scene of the occurrence without special tools or parts; tire disablement even if no spare tire is available; or damage to headlights, tail lights, turn signals, horn, or windshield wipers that makes them inoperative.”
Barbiturates and Benzodiazepines are both central nervous system depressants that have effects similar to the effects of alcohol. Barbiturates are prescription sedatives that are prescribed for acute anxiety, tension, and sleep disorders. Commonly prescribed barbiturates are mephobarbital (Mebaral) and pentobarbital sodium (Nembutal).

Benzodiazepines such as alprazolam (Xanax), diazepam (Valium), and chlordiazepoxide HCl (Librium) are prescribed to treat anxiety, acute stress reactions, and panic attacks. ProSom is a benzodiazepine that has a more sedating effect and can be prescribed for short-term treatments of sleep disorders. These medications are most commonly found in multi-colored tablets and capsules.

Prescription sedatives and tranquilizers can cause euphoria. They slow normal brain function, which may result in slurred speech, shallow breathing, sluggishness, fatigue, disorientation and lack of coordination, or dilated pupils. Upon initial use, a person usually feels sleepy and uncoordinated. Tolerance to the drug’s effects can occur over time resulting in a need for larger doses to achieve similar effects as those experienced initially. Higher doses cause impairment of memory, judgment and coordination, irritability, paranoia, and increased thoughts of suicide.

Barbiturates and Benzodiazepines should not be used with other medications unless specifically ordered by a physician. This includes other central nervous system depressants including prescription pain medications, some over-the-counter cold and allergy medications, or alcohol. Using these medications in combination with other substances, including alcohol, can be fatal.

Prescription depressants can be addictive resulting in withdrawal when the drug use is discontinued. Discontinuing use can result in seizures and other harmful consequences and should be done only under a physician’s supervision.

Prescription pain relievers are also known as prescription narcotics, narcotic analgesics, or opioids and are the most used and abused medications in use today. Commonly prescribed pain relievers include codeine, morphine, oxycodone, Percocet, hydrocodone and Vicodin. Morphine is one of the most effective drugs known for the relief of severe pain and is the standard against which new analgesics are measured. The use of morphine has increased significantly in recent years. Oxycodone is a pain reliever that is twice as potent as morphine. The most common oxycodone products are OxyContin®, Percocet, and Percodan. Hydrocodone is a legal opiate that is similar to morphine. There are over 200 medications that contain hydrocodone, but Vicodin (hydrocodone with acetaminophen) is one of the most commonly used and abused. Codeine and morphine in large enough concentrations will show up as chemical positives for opiates in DOT drug tests. The MRO may downgrade those positive results with a proof of a valid prescription but should issue a safety warning to the DER as per Part 40.327 as use of these substances certainly poses a risk to public safety.

When used as directed, these medications can relieve pain. They also cause drowsiness, constipation, and slowed breath. In some people, pain relievers also cause euphoria or feelings of well being by affecting the brain regions that mediate pain.

When taken as prescribed, pain relievers can safely manage pain effectively. Long-term use can result in an increased tolerance to the drug and requires higher doses to achieve the desired effects. But, ongoing use can also result in physical addiction as the body adapts to the presence of the drug. Withdrawal symptoms include restlessness, muscle and bone pain, insomnia, diarrhea, vomiting, and cold flashes.

Prescription pain relievers should not be used with other substances that depress the central nervous system such as alcohol, antihistamines, barbiturates, benzodiazepines, or general anesthetics as the interaction may result in severe respiratory depression and death.

Many transit professionals think that prescription pain relievers are safe because they have legitimate uses, however, they can be just as dangerous and addictive as illegal drugs.

Other prescription painkillers such as Tramadol and Flexeril have been responsible for several high profile accidents in the transit industry including the Staten Island Ferry accident of 2003 and the Maryland MTA light rail accidents at BWI airport in 2000.

Source: Partnership for a Drug-Free America
Urine Specimen Collection Guidelines Updated

The Department of Transportation Office of Drug and Alcohol Policy and Compliance (ODAPC) revised its Urine Specimen Collection Guidelines to be consistent with the changes to 49 CFR Part 40 that go into effect on August 25, 2008. The publication can be obtained from the ODAPC website at: www.dot.gov/ost/dapc/udsc.html. Revisions were made to the following sections of the Guidelines: Section 6: Collection Procedures, Section 8: Directly Observed Collection, and Section 10: Problem Collections.

To ensure that all specimen collections are conducted according to the regulations, all collectors should have a copy or access to the revised Guidelines and should be trained accordingly. Covered employers should contact their collection site(s) to make sure that facility management and collection personnel are aware of the changes and have been adequately trained on the revised procedures.

What Employers Need to Know About DOT Drug and Alcohol Testing

The DOT Office of Drug and Alcohol Policy and Compliance (ODAPC) recently published a manual of guidance and best practices for use by employers that are covered by the DOT drug and alcohol testing regulations. This manual entitled “What Employers Need to Know About DOT Drug and Alcohol Testing” is a companion to an earlier ODAPC publication entitled “What Employees Need to Know About DOT Drug and Alcohol Testing.” The employer version summarizes the regulatory requirements for each of the DOT modal administrations including the Federal Transit Administration (FTA), Federal Motor Carrier Safety Administration (FMCSA), Federal Aviation Administration (FAA), Federal Railroad Administration (FRA), Pipeline and Hazardous Materials Safety Administration (PHMSA), and the United States Coast Guard (USCG).

The publication provides guidance on program requirements and implementation, determining who is safety-sensitive, establishing a policy, selecting service agents, conducting employee and supervisor training, drug and alcohol testing requirements, employer response to rule violations, record keeping, and program compliance inspections and audits. A copy of the publication can be obtained from the ODAPC website at www.dot.gov/ost/dapc.

This publication, and the “SAP Guidelines” publication, were recently revised to reflect recent changes in Part 40 that were published in the Federal Register on June 25th, 2008, and will become effective on August 25, 2008.
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.