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FTA Drug & Alcohol Regulation Updates

U.S. Department of Transportation **Federal Transit Administration** Office of Safety and Security

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 forty-first in a series.

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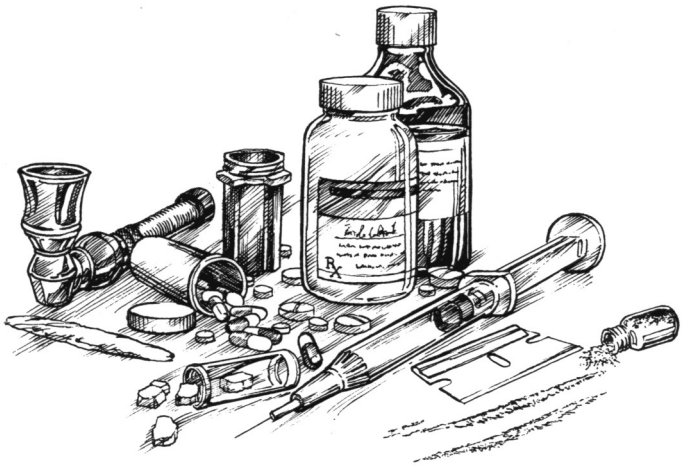
DOT Publishes Notice of Proposed Rulemaking

On February 4, 2010, the Department of Transportation (DOT) published a Notice of Proposed Rulemaking (NPRM) in Volume 75, Number 23, pages 5722-5732 of the Federal Register. The NPRM has six primary components that are designed to align the DOT drug testing procedures and definitions with the Department of Health and Human Services' (HHS) drug testing requirements. HHS laboratory procedures drive the DOT testing program as required by the Omnibus Testing Act and this NPRM is designed to harmonize DOT procedures with recent HHS changes. Comments were due to the docket by April 5, 2010. However, late-filed comments will still be considered to the extent practical. Comments can be submitted by going to the Federal eRulemaking Portal at www.regulations.gov. The implementation date of these changes is October 1, 2010 (Federal Register Vol. 75, No. 83/Friday, April 30, 2010/pgs. 22809-22810). The docket number is OST-2010-0026. The proposed changes are as follows:

- Definitions of the following terms were revised: Adulterated Specimen, Blind Specimen, Cancelled Test, Confirmatory Drug Test, Initial Drug Test, Invalid Result, Laboratory, and Limit of Detection.
- Definitions for the following terms were added: Alternate Responsible Technician, Certifying Scientist (CS), Certifying Technician (CT), Instrumented Initial Test Facility (IITF), Limit of Quantitation, Negative Result, Positive Result, Reconfirmed, Rejected for Testing, Responsible Person (RP), Responsible Technician (RT), and Split Specimen Collection.



- Introduction of an Instrumented Initial Testing Facility (IITF) that may be used by covered employers to conduct the initial drug screen tests. The IITF would be limited to providing test results to employers that are negative, negative dilute, and specimens rejected for testing. All other non-negative tests would be forwarded to an HHS-certified laboratory for additional testing.
- Inclusion of IITF procedures for conducting urine testing including the Initial Testing, Specimen Validity Testing (SVT), and procedures for transferring non-negative specimens to a full service laboratory to perform a full analysis of the specimen and report the results to the employer's MRO.
- Expand the list of drugs tested for to include Ecstasy and Eve including an initial test for Methylenedioxymethamphetamine (MDMA) and a confirmatory test tor MDMA, Methylenediosyamphetamine (MDA), and Methylenediosyethylamphetamine (MDEA).
- Required initial testing for 6-Acetylmorphines for opiate positives above the initial test cutoff concentrations of 2000ng/mL.
- Lower the initial test cutoff concentrations for Amphetamines to 500 ng/mL, and lower the confirmation test cutoff concentrations for Amphetamines and Methamphetamines to 250 ng/mL.
- Lower the initial test cutoff concentrations for cocaine to 150 ng/mL, and lower the confirmation test cutoff concentrations for Benzoylecgonine to 100 ng/mL.
- Require that IITFs report semi-annual test reports to employers and the DOT as appropriate.
- Require that nationally recognized Medical Review Officer (MRO) certification entities or subspecialty boards for medical practitioners have their qualifications, training programs, and examinations approved by HHS on an annual basis. The DOT sought comment on whether it should seek a shared approval process with the HHS and whether the MRO's continuing education requirement (12 CEUs every three years) should be eliminated in lieu of requiring MROs to be recertified every five years by an MRO certification board or subspecialty board.

REGULATORY CLARIFICATION

DOT Makes Interim Regulatory Changes Final

The Department of Transportation (DOT) published three notices in the Federal Register finalizing Interim Final Rules (IFR) that addressed issues that were outstanding or inconsistent with other programs or state law. The three final rules were published on February 25, 2010 in Volume 75, Number 37 of the Federal Register. All three rules also became effective on February 25, 2010.

The first rule change published on pages 8524-8526 adopted without change an IFR published on June 13, 2008. The rule authorizes employers covered under the DOT's drug and alcohol testing program to disclose to state commercial driver's licensing (CDL) authorities the drug and alcohol test results of CDL holders when a state law requires such reporting. Confidentiality of test results has always been a fundamental part of the DOT's regulation and, for the most part, §40.321 prohibits the release of individual drug or alcohol test results to third parties without the employee's specific written consent. However, the DOT views the legislative action taken by several states to require employers and certain service agents to provide individual test results to state agencies whenever CDL holders test positive as beneficial. Therefore, the IFR was adopted as a final rule without change.

The second rule change published on pages 8526-8528 of the above cited Federal Register addresses procedures for the use of a new alcohol screening device (ASD) which is qualified for use in DOT alcohol testing. This rule finalizes without change the Interim Final Rule amending 49 CFR Part 40 published on January 11, 2007 in Volume 72 of the Federal Register on page 1298. The final rule ensures that DOT- covered employers are allowed to use the breath tube Alcohol Screening Device (ASD) published on the National Highway Traffic Safety Administration's (NHTSA) Conforming Products List (CPL). As with other ASDs, this device may increase flexibility and lower costs for some employers for the initial screen test, but does not change the requirement to use an Evidential Breath Testing (EBT) device for confirmatory testing.

The third and final rule change can be found on pages 8528-8529. This rule authorizes DOT-covered employers to begin using the updated Paperwork Reduction Act Burden Statement, the current address of the DOT, and new DOT form numbers. Also, additional instructions were added to the reverse side of page 3 of the ATF. The added instruction says that tamper evident tape must not obscure the printed information. The legends in the test result boxes on the front of the ATF were also adjusted and printed in a smaller font so they do not obscure test results printed directly on the ATF. The new forms can be used immediately. The old forms can be used until supplies run out or January 1, 2011, whichever comes first. The date for usage of old ATF forms was extended as collection sites were reporting to DOT that large quantities of ATF's would have to be discarded (Federal Register Vol. 75, No. 90/Tuesday, May 11, 2010/pgs. 26183-26184).

The third rule change also updated the MIS form and its accompanying instructions to change the name of the Research and Special Programs Administration (RSPA) to the Pipeline and Hazardous Materials Safety Administration (PHMSA) to coincide with the renaming of the agency. The revised MIS form must be used in 2011 to report calendar year 2010 MIS data. Both revised forms can be found at www.dot.gov/ost/dapc/documents.html.

5th Annual Conference Best Yet!

Feedback from the fifth annual FTA Drug and Alcohol Program National Conference indicated that many thought the March conference held in Los Angeles was the best one yet. Several changes were made to this year's three-day conference that made it more informative, fun, and consistent with the needs of the attendees.

The first day provided specialized training for beginner Drug and Alcohol Program Managers (DAPMs) and Reasonable Suspicion Training. The main conference held the second and third days included information sessions as well as panel discussions on a variety of current topics and issues. Among the most popular sessions was the overview of regulatory changes, Notice of Proposed Rulemakings, and interpretations presented by Mark Snider of the USDOT Office of Drug and Alcohol Policy and Compliance (ODAPC). Also, the panel discussions on prescription and over-the-counter medications and the Role of Third Party Administrators sessions were well attended. Participants were able to walk away from the conference with specifics on how to review their collection sites for compliance, the role of the Medical Review Officer and Substance Abuse Professionals, and how to manage a program whether a large urban or rural transit system. Participants were also provided with resources for running a successful program and insight on how to troubleshoot common problems. New this year were several opportunities for attendees to meet and network with their industry peers.

What Did You Like Most About the Conference?

- "Being able to network with peers across the country."
- "The sessions were good for the very advanced and the new DAPM."
- "Panel Question and Answer session."
- "...ability to mix and match courses."
- "The approachability of all the presenters."
- "Scavenger game!"
- "Quality and expertise of the presenters."

Copies of the conference presentations can be downloaded from the Office of Safety and Security home page at http://transit-safety.fta.dot.gov/DrugAndAlcohol/Training/NatConf/2010/Default.asp.

Public Interest Exclusion Enforced

Subpart R of Part 40 includes a provision for a public interest exclusion (PIE) designed to protect the public from the effects of serious noncompliance by service agents. If a service agent fails or refuses to provide testing services consistent with the regulation or fails to cooperate with DOT or employer oversight activities, the DOT may institute a PIE that excludes that service agent from participation in the DOT's drug and alcohol testing program. There must be serious, uncorrected, noncompliance violations that affect safety, test results, privacy, employee due process, integrity of the testing program, or a lack of cooperation with the DOT to warrant the issuance of a PIE.

The Federal Aviation Administration (FAA) initiated a PIE against Michael R. Bennett and Workplace Compliance, Inc. because Mr. Bennett and his company provided MRO services to clients on DOT-regulated tests without having a qualified MRO verifying negative and non-negative test results. Mr. Bennett did not contest the allegations and the PIE was issued on July 31, 2009.

> *The PIE excludes Michael R. Bennett and Workplace Compliance, Inc., its officers, employees, directors, shareholders, partners or individuals associated with Workplace Compliance, Inc. from acting as a service agent or providing any drug and alcohol testing services to any DOT-regulated entity for the period beginning on July 31, 2009 and ending on July 31, 2014.*

The PIE was published in the Federal Register on November 17, 2009 and on a "list of Excluded Drug and Alcohol Service Agents" published on the DOT's website at www.dot.gov/ost/dapc. Mr. Bennett was also required to notify DOT-regulated employers for which *Workplace Compliance, Inc.* performed services of the PIE. DOT-covered employers are required to discontinue the use of Mr. Bennett's services as long as the PIE is in force. The issuance of a PIE does not result in the cancellation of drug or alcohol testing conducted by the service agent prior to the issuance of the PIE.

FOR YOUR INFORMATION

FTA Researches Impact of Benzodiazepines on Driving

Experts agree that prescription and over-the-counter medications can impact transit operators' ability to perform their functions in a safe manner. The extent of the impairment and the dosage levels at which impairment occurs, however, are not well documented for professional transit drivers.

The FTA has sponsored a research project entitled Post-Accident Testing Heuristics (PATH). PATH is a novel approach and method for researching the impact of benzodiazepines, commonly prescribed to promote sleep and counteract anxiety, on the driving performance of professional transit bus operators.

The experiment was designed to identify and quantify the impact of proto-typical, short half-life, benzodiazepines. The primary experiment was conducted using the Paducah (KY) Area Transit System's (PATS) Bus Driver Training Simulator. The driving simulator is a 360° wrap-around unit constructed in an 18-wheeler tractor-trailer rig with a large "bump-out" expanding middle section. The simulator was built using the front end of an actual Gillig 40-foot bus, and is an exact duplicate of the operator's cab of that motor bus.

The experiment was designed by Cahill Swift LLC and conducted by University of Iowa researchers with the support of the Kentucky Department of Transportation and PATS. Bus drivers with current CDLs were recruited from local transit, school bus, and coach operations.

The project was conducted from mid-September to November 2009. Experimental sessions consisted of four 10-minute drives conducted over a two-hour period. At the completion of the initial run, and again after the run at 40 minutes, 80 minutes, and 120 minutes, a saliva specimen was taken from the participant. The specimen was analyzed to provide the quantitative level of benzodiazepine in the participant's system.

Over the course of three experimental session-weeks, each driver received two different dose levels of the short-acting benzodiazepine – a minimum clinical dose and an average clinical dose – interspersed with one session in which the driver received a placebo. The order of doses and placebo was randomly assigned and unknown (double blind) to the experimenter and the participant.

The experiment resulted in data measuring the participants' driving performance, reaction times, and decisions made under stress under two drug dose levels and placebo control. This data is combined with head-mounted eye tracking data and video and with computerized psychomotor tests conducted immediately before each drive. The analysis of the large set of integrated data is underway. When complete, the analysis will enable the research team to comprehensively describe drug impacts/impairment, and to develop dose-response curves to relate the magnitude of drug impact to the dose of the benzodiazepine.

The results of this experiment and others like it will provide FTA and lawmakers with empirical data that will associate the relationship between prescription drug usage and transit safety and thus, has the potential to guide policy and law-making efforts in the future. The final results of this research are expected in the Fall of 2010.

QUESTIONS & ANSWERS

Q My collection site's EBT is getting very old and is becoming unreliable. I was planning to use some of my ARRA funds to purchase a new one. I have a lot of literature from manufacturers. How do I know if the equipment I am thinking about purchasing meets the regulatory requirement?

A Only testing devices that are listed on the National Highway Traffic Safety Administration's (NHTSA) Conforming Products Lists (CPLs) can be used to conduct alcohol testing under the Department of Transportation's (DOT) alcohol testing regulations. The initial screen test may be conducted using an evidential breath testing (EBT) device or a non-evidential alcohol screen device (ASD) using breath or saliva. The confirmatory test can only be conducted using an EBT.

The list of instruments on the NHTSA approved CPL for alcohol screen devices was recently expanded and updated. The new list was published on the December 15, 2009 Federal Register, Volume 74, Number 239, pages 66398-66400. Fourteen new breath alcohol screening devices were added and one device was removed. Thirty-nine instruments are currently on the list.

On March 11, 2010, NHTSA added four new EBTs and updated the mobility status of an existing instrument. With these additions, the total number of EBTs has risen to eighty-eight. When consulting the list, please note that only those Make/Models that do not have an asterisk (*) are considered EBTs. The list was published in the March 11, 2010 Federal Register, Volume 75, Number 47, pages 11624 – 11627.

The list of approved alcohol screening devices and evidential breath testing devices can be found by going to www.dot.gov/ost/dapc and clicking on the appropriate topic under "Important Links."

COMMON AUDIT FINDINGS

Training

The training requirements for safety-sensitive employees specified in the FTA drug and alcohol testing program (§655.14) have remained the same since the regulation was first published. Early on, auditors seldom found issue with system compliance with this requirement. However, in recent years more and more systems are noncompliant in this area. A discussion with transit system administrators has revealed that in many cases the training requirement has been overlooked due to personnel changes in drug and alcohol program managers (DAPMs), budget limitations resulting in reduced training budgets, reduced agency priorities, degradation (time, content and emphasis) of new employee orientation, lax documentation and simply, lack of oversight.

The FTA drug and alcohol testing regulation requires each employer to establish an education training program for all covered employees. The program must include a general education component and substance abuse awareness training for all safety-sensitive employees. The general education component of the program (§655.14(a)) requires each employer to *display* and *distribute* informational material about the effects of drugs and alcohol to every covered employee. In addition, each employer must display and distribute a community service hot line telephone number to help employees who may be experiencing problems with prohibited drug use or alcohol misuse.

The regulation (§655.14(b)) also requires that covered employers provide a minimum of sixty minutes of training to all safety-sensitive employees on the effects and consequences of **prohibited drug use on personal health, safety, and the work environment.** This training must also address the signs and symptoms that may indicate drug use. Training programs that are less than sixty minutes long, or programs that address other topics (i.e., policy, alcohol) within the sixty minutes are not compliant. Likewise, programs that require employees to watch a video that is less than sixty minutes in length without any additional training do not meet the regulatory requirement.

Training safety-sensitive employees on the effects and consequences of alcohol misuse is not required by the FTA regulation. However, information concerning the effects of alcohol misuse on the individual's health, work , and personal life, as well as signs and symptoms of an alcohol problem, must be provided as part of the general education program as discussed previously.

& Rx OTC MEDICATIONS

Muscle Relaxants—Use with Caution

Muscle relaxants are drugs that are prescribed to alleviate symptoms such as muscle spasms, pain and hyperreflexia. It is a term used to refer to skeletal muscle relaxants and smooth muscle relaxants or antispasmodics.

Skeletal muscle relaxants are used to relax certain muscles and relieve the stiffness, pain, and discomfort caused by strains, sprains, or other injury to muscles. These drugs act in the central nervous system to cause their desired effect and some of their less desirable side effects. As with all prescription medications, transit professionals should weigh the risks of taking these medications against the benefits of taking them, and the potential impact that use will have on their ability to perform safety-sensitive functions. This decision should be made between the transit professional and his/her medical practitioner who is fully aware of the safety-sensitive job duties of the transit employee. The employee should also notify the employer of any prescription that may affect their ability to operate or perform their safety-sensitive duties as per employer policy. If the employer does not have a Rx notification policy, then they should address this issue in their substance abuse policy as soon as possible.

Skeletal muscle relaxants may cause blurred vision, clumsiness, or unsteadiness in some people. They may also cause people to feel drowsy, dizzy, lightheaded, faint, or less alert. Drowsiness may be increased when used in concert with alcohol and other drugs that affect the central nervous system, such as antihistamines, sedatives, tranquilizers, sleep medications, prescription pain medicine, barbiturates, benzodiazepines, anti-seizure medications, anesthetics, or other muscle relaxants.

In many cases transit professionals should refrain from taking muscle relaxants all together while performing safety-sensitive duties. Even if the prescribing medical practitioner determines that use of the medication is acceptable or provides a modified dosing schedule, transit professionals should make sure they know how they will react to muscle relaxants **before** they perform safety-sensitive duties.

FDA WARNING:

TRANSIT PROFESSIONALS SHOULD NOT DRIVE, USE MACHINES, OR DO ANYTHING ELSE THAT COULD BE DANGEROUS IF THEY ARE DIZZY OR ARE NOT ALERT, WELL-COORDINATED, AND UNABLE TO SEE WELL.

The dose of these medications will be different for different individuals. Therefore, it is imperative that transit professionals follow their doctor's orders or the directions on the label exactly as written. No one should use muscle relaxants prescribed for another person, or use a dose that is larger than or more frequent than what is prescribed.

Commonly prescribed muscle relaxants include:

- Carisoprodol — Soma
- Chlorzoxazone — Paraflex, Parafon Forte DSC, Remular-S
- Cyclopenzaprine — Flexeril
- Metaxalone — Skelaxin
- Orphenadrine — Norflex, Banflex
- Tizanidine — Zanaflex
- Methocarbamol — Robaxin, Robaxin-750

Sources of Community Service Hot Line Numbers

- Alcohol Abuse and Crisis Intervention: 800-234-0246
- Al-ateen: 800-352-9996
- Alcohol and Drug Abuse Helpline and Treatment: 800-234-0420
- Alcohol Hotline Support & Information: 800-331-2900
- Alcoholics Anonymous – 800-870-3795
- American Council on Alcoholism Help Line – 800-356-9996
- Boys Town National Hotline 800-448-3000
- Local United Way
- Narcotics Anonymous – See Local Directory
- National Cocaine Hotline: 800-COCAINE (262-2463)
- National Council on Alcoholism and Drug Dependence Hope Line 800- 622-2255
- National Directory of Drug Abuse and Alcoholism Treatment and Prevention Programs—U.S. Public Health Service
- National Drug Information Treatment and Referral Hotline: 800-662-HELP (4357)
- The Alcohol & Drug Addiction Resource Center 800-390-4056
- Your State Alcohol and Drug Abuse Clearinghouse
- Your State Alcohol and Drug Abuse Agency(ies)
- Yellow Pages directory under "Social Service Agencies"
- Your Municipal Government Department of Social Services, or equivalent
- Your Employee Assistance Program or Health Insurance Provider

RESOURCES

FTA Drug and Alcohol MIS Project Office: (617) 494-6336
FTA home page: http://www.fta.dot.gov
- Center for Substance Abuse Prevention: http://prevention.samhsa.gov
- DHHS-Certified Laboratories: http://workplace.samhsa.gov/DrugTesting/Level_1_Pages/CertifiedLabs.aspx
- FTA Office of Safety & Security: http://transit-safety.fta.dot.gov

FTA, Office of Safety and Security Clearinghouse
- Best Practices Manual: FTA Drug & Alcohol Testing Program, Revised 2008
- DOT's 10 Steps to Collection Site Security and Integrity
- DOT's Direct Observation Procedures Poster, revised August 31, 2009
- Drug and Alcohol Consortia Manual
- Drug and Alcohol Testing Results: 1995 through 2007 Annual Reports
- FTA Drug and Alcohol Program Assessment
- Implementation Guidelines for Drug and Alcohol Regulations in Mass Transit, Revised 2003
- Prescription and Over-The-Counter Medications Toolkit
- Reasonable Suspicion Referral for Drug and Alcohol Testing (Leader's Guide & Video)
- Substance Abuse Professional Guidelines, revised August 31, 2009
- Urine Specimen Collection Procedures Guidelines, revised August 31, 2009
- What Employees Need to Know About DOT Drug and Alcohol Testing, revised August 31, 2009
- What Employers Need to Know About DOT Drug and Alcohol Testing, revised August 31, 2009

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
- DOT's Ten Steps Video
- MIS Data Collection Form and Instructions

FTA Drug & Alcohol Regulation Updates

U.S. Department of Transportation **Federal Transit Administration** Office of Safety and Security

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: One Page MIS Form

November 30, 2006 Federal Register Vol. 71, Pages 69195-69198
Primary Topic: Applicability of FTA and USCG Regulations to Ferryboats

January 9, 2007 Federal Register Vol. 72, Pages 1057-1058
Primary Topic: Revised Testing Rates

49 CFR Part 40, Procedures for Transportation Workplace Drug Testing Programs

Revised: December 19, 2000 Federal Register Vol. 65, Pages 79462-79579

August 1, 2001 Federal Register Vol. 66, Pages 41943-41955
Clarifications and Corrections to Part 40; Common Preamble to Modal Rules

Final Rule Changes
August 23, 2006 Federal Register Vol. 71, Pages 49382—49384; Expanded List of SAP Qualifications

June 25, 2008 Federal Register Vol. 73, Pages 35961-35975; Specimen Validity Testing

November 20, 2008 Federal Register Vol. 73, Pages 70283-70284; Direct Observation Collections

February 25, 2010 Federal Register Vol. 75, No. 37, Pages 8524-8526; Release of Results to State CDL Authorities

February 25, 2010 Federal Register Vol. 75, No. 37, Pages 8526-8528; Permits New ASD

February 25, 2010 Federal Register Vol. 75 ,No. 37, Pages 8528-8529; New ATF and MIS Forms

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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.

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