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

FTA Drug And Alcohol Regulation *Updates*

Winter 2005 **Issue 29**

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 twenty-ninth in a series.

Inside....

MIS Reports Due March 15

All transit systems and safety sensitive contractors subject to the Federal Transit Administration's (FTA) drug and alcohol testing regulations must file annual Management Information System (MIS) reports for the 2004 calendar year by March 15, 2005. In 2004, the FTA joined the four other Department of Transportation (DOT) agencies in adopting a single one-page form for use in reporting drug and alcohol test results. The form is provided in 49 CFR Part 40 and was published in the Federal Register on July 25, 2003 (§40.25 and Appendix H).

The FTA also strongly encouraged electronic filing of MIS reports. Implementation of the new form and electronic filing procedure went very smoothly and thus, the same procedures are in place for reporting the CY 2004 data.

All FTA grantees and states have been selected to report 2004 MIS information to FTA. Agencies are strongly encouraged to file their reports electronically. However, those who choose to submit hard copies can do so by obtaining the forms from the FTA Office of Safety and Security website and once completed, mail them to: FTA Drug and Alcohol MIS Project Office, DTS-781, Volpe National Transportation Systems Center, 55 Broadway, Kendall Square, Cambridge, MA 02142.

Electronic reporters should file online at http://damis.dot.gov. To file each grantee must use the user ID and password issued for their agency. They should provide user Ids and passwords, sent to them by FTA, to their contractors/subrecipients. If a grantee has a new contractor or subrecipient or if the list of contractors/subrecipients is incorrect, the agency should contact the FTA Drug and Alcohol MIS (DAMIS) Project Office to request additional passwords. The DAMIS office can be reached at (617) 494-6336, or fta.damis@volpe.dot.gov.

State DOTs are to review the Section 5311 subrecipients' submittals for accuracy, return for correction if necessary, and accept to submit. Similarly, grantees must check the accuracy of their safety-sensitive contractors' reports. The grantee/State DOT must officially accept the submittal for it to be considered complete. Once all information has been completed and all errors and warnings have been addressed, an official of the covered employer must sign the submission before it is mailed. Internet submissions can be signed by clicking the *Electronically Sign* button.

Random Rates Unchanged

The USDOT Office of Drug and Alcohol Policy & Compliance (ODAPC) outlined the annual minimum drug and alcohol random testing rates established for each DOT mode for 2005 on its website (www.dot.gov/ost/dapc/rates.html). The Federal Transit Administration (FTA) random testing rate for drugs remains at fifty percent (50%) while the random testing rate for alcohol remains at ten percent (10%).

The Federal Motor Carrier Safety Administration (FMCSA) also requires random testing at the 50 % rate for drugs and 10 % rate for alcohol, while the Federal Aviation Administration (FAA) and Federal Railroad Administration (FRA) test at the 25% rate for drugs and 10% rate for alcohol. Employers and third party administrators (TPAs) subject to more than one DOT agency drug and alcohol testing rule may combine covered employees into a single random selection pool. However, if the employer/TPA fall under the jurisdiction of DOT modes with differing testing rates, the employer/TPA must test at or above the highest minimum annual random testing rates of the modes.

Did You Contact Us?

All future editions of this newsletter will be distributed electronically unless otherwise requested. If you wish to receive future issues by e-mail, you must contact us with your e-mail address. If you wish to continue receiving hard-copy versions through the mail, you must also contact us to request this option. If you do not contact us to indicate your preference, your name will be removed from the mailing list. To continue to receive future editions of the newsletter, please contact the editor at rlsasc@mindspring.com, call (937) 299-5007, or fax (937) 299-1055.

INTERIM FINAL RULE

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

Notice of Interpretation:
April 22, 2002
Federal Register Vol. 67,
Pages 19615-19616
Primary Topic: FTA/USCG regulation applicability to ferry boats.

The information presented on this page should be used to update Chapter 7 of the revised *Implementation Guidelines*.

Specimen Validity Testing

On November 9, 2004, the Department of Transportation (DOT) issued an interim final rule (IFR) amending its drug testing procedures to change instructions to laboratories and Medical Review Officers (MROs) with respect to adulterated, substituted, and diluted specimen results. The IFR was published in the Federal Register Vol. 69, No. 216, pages 64865-64868. This change to 49 CFR Part 40 makes the rule consistent with the new specimen validity testing requirements established by the U.S. Department of Health and Human Services (HHS) that went into effect on November 1, 2004 (see *Updates*, Issue 27, page 2) and are referred to as the HHS Mandatory Guidelines. The new IFR replaces the previously issued IFR published in the Federal Register on May 28, 2003 (see *Updates*, Issue 25, page 2) that established validity testing procedures for DOT mandated drug testing in the absence of the HHS standards.

Previously, the rule recognized two tiers of substitute specimens. Specimens having creatinine levels less than 2 mg/dL were considered to be substituted requiring medical review by an MRO, while specimens with creatinine levels between 2 and 5 mg/dL were also considered to be substituted, but required MROs to have employers send employees for a retest under direct observation. Under the new IFR, specimens are determined to be substitute only if the creatinine levels are below 2mg/dL. The higher tier, creatinine levels between 2 and 5 mg/dL, no longer exist as substitute and all references to such have been removed from Part 40. MRO medical reviews and verification are required for substituted specimen results.

Specimens are considered dilute when the creatinine concentration is greater than or equal to 2 mg/dl but less than 20 mg/dL and the specific gravity is greater than 1.0010 but less than 1.0030. MRO medical reviews and verification are not required for dilute specimens. The IFR also adopts HHS instructions that direct laboratories to perform validity tests for oxidizing adulterants and additional validity test when certain conditions (e.g., abnormal physical characteristics) are observed.

The IFR also makes specimen validity testing instructions for the laboratories consistent with the HHS Mandatory Guidelines as well as the laboratory results reporting requirements.

The DOT differs from the HHS Mandatory Guidelines in three major areas. First, the DOT authorizes, but does not require laboratories to perform specimen validity testing. Laboratories that conduct specimen validity testing of DOT specimens, however, must do so in accordance with the testing requirements established in the HHS Mandatory Guidelines. Second, even though specimens with creatinine levels greater than or equal to 2 mg/dL but equal to or less than 5mg/dL are considered negative dilute rather than substitute, the MRO is still required to have the employer send the employee immediately for a recollection under direct observation. And, finally, under the DOT rule, laboratories are required to provide creatinine and specific gravity numerical values for all specimens they report to the MRO as being negative dilute.

For additional information regarding this IFR, contact Jim L. Swart, Deputy Director, ODAPC at (202) 366-3784 or jim.swart@ost.dot.gov.

TSI Offers Training

The Transportation Safety Institute (TSI) provides a two and one-half-day substance abuse management course as part of its core curriculum. The course assists participants with conducting an evaluation and self-assessment of their respective agency's substance abuse program and compliance with FTA regulations. The course involves lecture, group discussion and time for participants to evaluate their programs and ask questions. Classes are available for a materials fee of $25 per participant. Classes will be offered in Kansas City, MO on March 2-4 and Lubbock, TX on June 21-23. For more information, call (405) 954-3682.

UPDATES

The following index may be used for quick reference to *FTA Drug and Alcohol Regulation Updates* articles beginning with Issue 17 (Winter 2001) which coincides with the publication of the revised 49 CFR Part 40 and Part 655.

FTA Drug and Alcohol Regulations Index

Testing Procedures Index

Prescription Over-the Counter Medications Index

Where To Find?.....

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

Revised:
December 19, 2000
Federal Register Vol. 65,
Pages 79462-79579.
Primary Topic: Procedures for Transportation Workplace Drug and Alcohol Testing Program Revised Final Rule
(49 CFR Part 40)

July 25, 2003
Federal Register 68
Pages 43946-43964
Primary Topic: One Page MIS Form

January 22, 2004
Federal Register Vol. 69
Pages 3021-3022
Primary Topic: Expand List of SAPS

Technical Amendments:
August 1, 2001
Federal Register Vol. 66
Pages 41943-41955
Primary Topic: Clarifications and Collections to Part 40; Common Preamble to Modal Rules

Interim Final Rule
May 28, 2003
Federal Register Vol. 68
Pages 31624-31627
Primary Topic: Substitute and Dilute Specimens

The information presented on this page should be used to update Chapters 7 and 9 of the revised *Implementation Guidelines*.

TECHNICAL ASSISTANCE

Where to Find? .....

DHHS Labs

The current list of DHHS certified labs is published the first week of each month and is printed in the Federal Register under the Substance Abuse and Mental Health Services Administration (SAMHSA) heading. Only those labs certified can be used for FTA drug testing. The list should be checked monthly as new labs are being added and others are being removed.

Website location: http://www.workplace.samhsa.gov/ResourceCenter/lablist.htm

To verify the certification status of a laboratory, DHHS has established a telephone HELPLINE (800) 843-4971.

The information presented on this page should be used to update Chapter 7 and 12 of the revised *Implementation Guidelines*.

Oversight Remains Responsibility of Grantee

Even though most FTA grantees/subrecipients contract out their drug and alcohol testing services to various service agents (e.g., collection sites, laboratory, MRO, BAT and SAP), they cannot contract away their compliance responsibilities. If an agency's service agents do not perform testing services consistent with the regulations, the agency's good faith effort is not a defense for noncompliance (§40.15(c)).

Many grantees/subrecipients assume that their contractors are performing their duties in a compliant manner and fail to monitor and provide oversight. In many cases, this assumption is wrong with significant consequences for the transit agency. Even though the regulation does not stipulate how an employer should monitor its service agents, the following activities have become standard industry practice:

- Conduct periodic mock collections to identify procedural flaws;
- Conduct periodic review of service agent employee credentials including training documentation;
- Investigate any employee reports of flawed procedures;
- Provide service agents with copies of appropriate DOT guidelines, regulations, and related materials;
- Monitor cancelled tests and require detailed explanations for each;
- Include minimum performance standards in contracts that provide disincentives for cancelled tests or non-performance.

Transit agencies must document their oversight process and take corrective action when necessary. If a service agent is unwilling or unable to perform their duties consistent with the regulations, the transit agency should obtain the service elsewhere.

Common Collection Mistakes Should be Avoided

Even though 49 CFR Part 40 Subpart C requires collectors to receive training and demonstrate proficiency, collectors are still making common mistakes that are compromising the testing process. One of the most common mistakes is that collectors initial the tamper evident seal while the seal is still affixed to the Chain of Custody and Control Form (CCF) prior to placing it on the bottle. Another common mistake is that the donor dates the seal rather than the collector. This is incorrect. Once the urine is poured from the collection cup to the primary and split specimen bottles and the caps are secure, the collector should place the seals on the bottles. It is only once the labels are on the bottles that the collector writes the date on the seals and then requests the employee to initial the labels verifying that the specimen is his/hers.

One way to determine if these mistakes are being made is to review the employer's copy of the CCF and see if the date has come through the carbon on the bottom right of the form. If the date shows, this indicates that seals were dated while affixed to the CCF rather than the bottle.

ODAPC 411

The Office of Drug and Alcohol Policy and Compliance (ODAPC) established a new electronic information dissemination system called ODAPC 411. The email list is open and free to all individuals interested in receiving electronic news, updates and information related to DOT's Workplace Drug and Alcohol Testing Procedures as published by ODAPC. To subscribe, enter your email address on the ODAPC website in the space indicated under *News/ Updates by E-Mail* at www.dot.gov/ost/dapc/email. In addition to the electronic mail distribution system, news and information will continue to be available on the ODAPC website at www.dot.gov/ost/dapc/news.

RX & OTC MEDICATIONS

Antihistamines Impair Driving

Since the late 1980's, the National Transportation Safety Board (NTSB) has investigated numerous accidents caused in part by the standard use of over-the-counter (OTC) medications. Sedating antihistamines obtained over-the-counter contributed to a large number of these accidents.

Antihistamines can cause drowsiness, impaired coordination, inability to concentrate and dizziness. Medical research has found that the antihistamine diphenhydramine, found in Benadryl, Tylenol Severe Allergy, and Sominex, actually causes greater impairment than alcohol. University of Iowa researchers found that the standard dose of antihistamine contained in Benadryl and similar medicines had a greater effect than a few drinks on a driver's ability to match the speed of the vehicle ahead, adversely effected steering stability and increased the likelihood of crossing into the oncoming lanes[1].

The researchers tested performance using a driving simulator to test participants' abilities once after taking diphenhydramine, once using a non-drowsy antihistamine (fexofenadine found in Allegra), once with a placebo and once when the participant had a blood-alcohol concentration of 0.1 percent. The participants' impairment, as evidenced by following and steering abilities, was significantly worse after the participants took diphenhydramine than when they took alcohol. The number of times the participants crossed into the oncoming lane was twice as great after taking diphenhydramine as after taking fexofenadine or the placebo. Researchers also determined that the participants' assessments of how drowsy they were did not correlate with their performance, suggesting that people who take antihistamines may not be able to judge when they are impaired, further adding to the risk.

Antihistamines are used by millions of Americans that suffer from hay fever and allergies. Most of these medications come with warning labels cautioning that they may cause drowsiness and should not be used while operating heavy machinery. There are also warnings about mixing antihistamines with alcohol. Unfortunately, people often don't read or ignore the warnings.

Several European countries require drug manufacturers to color-code their packages with symbols that indicate which drugs may cause drowsiness or impair a person's ability to drive or operate heavy machinery safely. The National Transportation Safety Board has recommended that the FDA establish a similar labeling requirement for over-the-counter drugs.

In the mean time, employers must educate employees regarding the dangers associated with the use of over-the-counter medications, especially antihistamines that cause drowsiness. Employees should be taught how to read labels, how to talk to physicians and pharmacists, how to be aware and recognize side effects, and how to tell their supervisors if they feel impaired as a result of medications, lack of sleep or other causes.

Allergy and hay fever sufferers have non-drowsy, antihistamine alternatives (e.g., Claritin, Allegra and Zyrtec). Claritin, once available only by prescription, is now available over-the-counter. Many individuals, however, are not aware of the difference between sedating and non-sedating antihistamines and may use them interchangeably. The over-the-counter forms are easiest to obtain since they do not require a prescription, but typically cause performance impairment (except for Claritin), while the prescription alternatives typically do not impair performance, but are more difficult to obtain. Employees should speak with their health care provider or pharmacist about the potential side effects of medications and should seek out non-drowsy alternatives if possible.

The FTA strongly encourages transit systems to directly notify safety-sensitive employees regarding the dangers of sedating antihistamine use and other over-the-counter and prescription medications through training, brochures, notices, or other means of communication that have proven effective.

[1]Weiler, John M., **Effects of Fexofenadine, Diphenhydramine, and Alcohol on Driving Performance**, Annals of Internal Medicine, March 7, 2000, Volume 132, Issue 5, pages 354-363.

Where to Find? .....

Conforming Products List
Evidential Breath Testing (EBT) Devices
July 21, 2000
Federal Register Vol.65
Pages 45419 - 45423
Primary Topic: Conforming Products List (CPL)
Website location: www.nhtsa.gov/people/injury/alcohol

Note: This list will be updated periodically.

Non-evidential Testing Devices
May 4, 2001
Federal Register Vol.66
Pages 22639 - 22640
Primary Topic: Initial Alcohol Screening Devices

Note: This list will be updated periodically.

FTA Drug & Alcohol Discussion Forum:
http://transit-safety.volpe.dot.gov/Safety/BBS

Drug and Alcohol Audit Questions
http://transit-safety.volpe.dot.gov/Safety/DATesting/Audit/default.asp

The information presented on this page should be used to update Chapter 5 of the revised *Implementation Guidelines.*

Resource Materials

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 following address to include them on the mailing list. This publication is free.

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FTA Office of Chief Counsel: http://www.fta.dot.gov/about/offices/hq/4956_4944_ENG_HTML.htm
FTA Office of Safety & Security: http://www.fta.dot.gov (then click on Safety & Security)
FTA Letters of Interpretation: http://www.fta.dot.gov/library/legal/dral/02toc.htm
DHHS-Certified Laboratories: http://www.workplace.samhsa.gov/ResourceCenter/lablist.htm
Center for Substance Abuse Prevention: http://prevention.samhsa.gov

FTA, Office of Safety and Security Clearinghouse: (617) 494-2108

Best Practices Manual: FTA Drug & Alcohol Testing Program
Drug and Alcohol Consortia Manual
Drug and Alcohol Testing Results: 1995, 1996, 1997, 1998, 1999, 2000 and 2001 Annual Reports
Implementation Guidelines for Drug and Alcohol Regulations in Mass Transit, Revised 2003
Reasonable Suspicion Referral for Drug and Alcohol Testing (Leaders' Guide & Video)
FTA Drug and Alcohol Program Assessment
Prescription and Over-The-Counter Medications Toolkit

USDOT Drug and Alcohol Documents FAX on Demand: 1 (800) 225-3784
USDOT, Office of Drug and Alcohol Policy and Compliance: (202) 366-3784 or http://www.dot.gov/ost/dapc/

Urine Specimen Collection Procedures Guideline
Substance Abuse Professional Guidelines

Produced by:	Published by:	Edited by:	Illustrated by:
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