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

FTA Drug And Alcohol Regulation *Updates*

Spring 2004 **Issue 27**

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-seventh in a series.

Inside....

ODAPC Director Appointed

On May 17, John A. Bobo, Jr. was appointed the U.S. DOT's Director of the Office of Drug and Alcohol Policy and Compliance (ODAPC). The ODAPC's mission is to enhance public safety within U.S. transportation industries by ensuring that DOT's drug and alcohol policies are implemented in a consistent, fair and efficient manner. The Office provides program review, compliance evaluation, and issues consistent guidance material for FTA and the other DOT operating administrations.

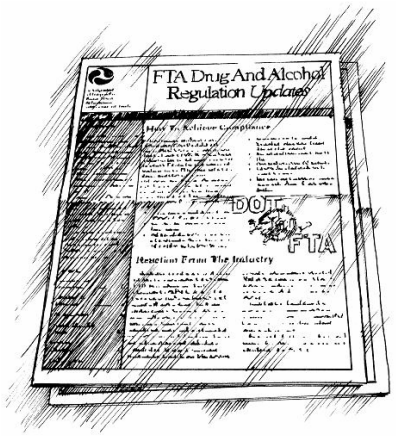
Mr. Bobo previously served as the Director of the National Law Center at the American Prosecutors Research Institute (APRI), a non-profit organization that provides research, training and technical assistance to prosecutors, judges, officers, and others in the law enforcement community. In 2002, Mr. Bobo assisted the White House's Office of National Drug Control Policy, in forming and releasing its drugged driver policy statement.

Mr. Bobo also served as an Assistant District Attorney in the District Attorney General's Office in Maryville, TN where his primary area of responsibility was serving as liaison to the 5th Judicial Drug Task Force. In Chattanooga, TN he prosecuted drug-related murder cases and narcotics cases. He served as a special vehicular homicide/impaired-driving prosecutor and served on the Board of Directors of a local alcohol and drug rehabilitation facility.

In his new position, Mr. Bobo can be reached at (202) 366-3784 or john.bobo@ost.dot.gov.

Contact Us About Future Editions!

The electronic publication and distribution of future editions of this newsletter will be phased in over the next six months. This article is the second of three announcements that will be made before the electronic publication process goes into full effect. This edition and the Summer 2004 edition scheduled for publication in August will be distributed both electronically and by mail. The Fall 2004 edition scheduled for publication in November will be distributed via the Internet to those who have provided email addresses. Hard copies will be mailed only to those individuals who have requested to continue receipt of the newsletter via the U.S. Postal Service.



Persons that have failed to contact us to confirm their continued interest or to request their preferred method of distribution will be purged from the database. At the time of this newsletter publication, nearly fourteen percent of the individuals on the database had already contacted us with their email addresses.

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.

FTA Program Represented at CTAA Expo

The FTA Drug and Alcohol Program will once again have an exhibit at the CTAA Expo to be held in Seattle on June 16-17. FTA representatives will be there to distribute resource materials including copies of the *Implementation Guidelines, Best Practices Manual* and the *Prescription and Over-the-Counter Medications Toolkit.* They will be available to answer questions and demonstrate the FTA Office of Safety and Security web site including the FTA Drug and Alcohol Discussion Forum. They will be in Booth 113.

DHHS Proposed Rules

Where To Find?.....

49 CFR Part 655, Prevention of Alcohol Misuse and Prohibited Drug Use in Transit Operations

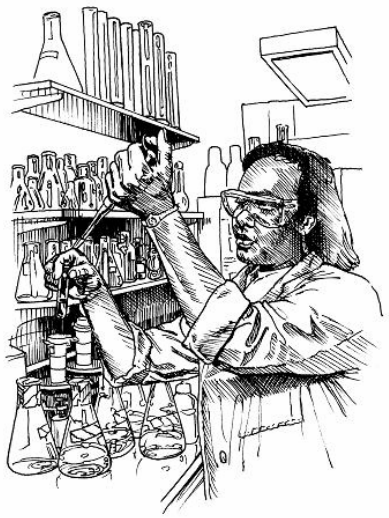
August 9, 2001
Federal Register Vol. 66
Pages 41996 - 42036

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*.

DHHS Establishes Validity Test Standards



On April 13, 2004, the Substance Abuse and Mental Health Administration (SAMHSA) of the Department of Health and Human Services (DHHS) established standards for determining the validity of urine specimens collected under the Mandatory Guidelines for Federal Workplace Drug Testing Programs. These standards were published in the Federal Register Vol. 69, No. 71, pages 19644-19673. The standards were created to ensure that specimen validity testing (SVT) and reporting procedures are uniformly applied to all Federal agency urine specimens when a validity test is conducted.

Revised standards include, among other things, definitions of SVT related terms, SVT requirements, reporting requirements, clarification of MRO qualifications and responsibilities, donor challenge procedures and expansion of the existing performance-testing program and laboratory inspection program. Highlights of these revisions include:

- Validity tests are <u>required</u> on all specimens collected under the Mandatory Guidelines.
- Laboratory criteria were established to report a specimen as adulterated, substituted, invalid, or dilute. pH cutoff levels were established for adulterated specimens. Specific gravity and creatinine cutoff levels were established for substituted specimens. A substitute specimen is defined as one that has a creatinine concentration of less than 2 mg/dL and the specific gravity is less than or equal to 1.0010 or greater than or equal to 1.0200 on both the initial and confirmatory creatinine tests.
- The DHHS will begin including a list of known adulterants in the monthly Federal Register notices that list the laboratories that meet minimum standards to engage in urine drug testing for Federal agencies. The list will be revised as new adulterants are identified.

The revisions are consistent with the DOT Interim Final Rule (IFR) published in the Federal Register (Vol. 68, Pages 31624) on May 28, 2003 (See *Updates*, Issue 25, page 2) that established new dilute and substitute specimen criteria to be used for DOT mandated drug testing. However, the DOT IFR requires the MRO to define a specimen with a creatinine concentration below the cutoff levels (< 2 mg/dL) as substitute and requires the MRO to require the employer to send the employee for a retest under direct observation if the creatinine level is between 2 and 5 mg/dL. The revised Guidelines simplify the procedure by requiring the laboratories to report specimens below the newly established cutoff levels (< 2mg/dL) as substitute.

Even though the Mandatory Guidelines are established only for federal safety-sensitive employees eligible to be tested and does not directly address DOT/FTA covered employees, these standards are typically followed by the DOT. Consequently, the DOT is expected to publish a notice of proposed rulemaking (NPRM) by October and a final rule by November that incorporates these provisions in 49 CFR Part 40 making the DOT rule consistent with the Mandatory Guidelines for Federal Workplace Drug Testing Programs.

The new standards become effective on November 1, 2004. The only portion of the revised guideline that is open to further comment is the standard regarding the creatinine criteria for substitute specimens. Comments must be received by June 14, 2004 and must include the agency name and docket number (04-7985) of the rulemaking. Submissions to the docket must be made by e-mail at <u>wvogl@samhsa.gov</u>, fax at (301) 443-3031, or mail to 5600 Fishers Lane, Rockwall II, suite 815, Rockville, Maryland 20857.

DHHS Proposed Rules

DOT Encourages Comments on DHHS' Alternative Testing NPRM

On May 13, 2004, the DOT Office of the Secretary, issued an informational notice in the Federal Register (Vol. 69, No. 93, page 26641) to notify individuals interested in the DOT drug testing program that the DHHS was proposing important new drug testing procedures. The DHHS proposal was published in the Federal Register (Vol. 69, No, 71, pages 19673-19732) on April 13, 2004.

The proposed revisions to the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Guidelines) include scientific and technical guidelines for alternative drug testing methods including hair, sweat, and oral fluid specimens in addition to urine specimens; scientific and technical guidelines for using on-site tests to test urine and oral fluid at the collection site; requirements for the certification of instrumented initial test facilities; and added standards for collectors, on-site testers and medical review officers.

Even though the Guidelines do not apply to DOT regulated entities directly, DOT covered employers, employees, and service agents involved in the DOT testing program should be aware of the DHHS notice since the DHHS and DOT drug testing procedures have a statutorily recognized relationship established in the Omnibus Transportation Employee Testing Act of 1991 and the Guidelines have historically served as the basis for the DOT testing procedures defined in 49 CFR Part 40. The DHHS final rule that results from the rule making process will consequently, be considered for incorporation in future revisions to Part 40. Thus, the DOT recommends that DOT-covered entities review the DHHS proposals and make comments accordingly.

Inclusion of alternative testing methods (hair, sweat, and oral fluid) are proposed to complement urine drug testing and thwart efforts of those trying to beat the drug test through adulteration, substitution, and dilution. Use of these methods is not a requirement, but provide an alternative that employers can use when appropriate. No one method is considered to be the best, as each specimen type has different attributes and limitations that must be taken into consideration when determining its application for use. Not all of the testing methods have the capability to test for all required drugs at acceptable levels of accuracy. In addition, each method has varying ability to detect some drug classes. Thus, given the current state of the science, special awareness is required to select the most appropriate type of specimen to be collected from a specific donor in a specific situation.

Hair testing increases the time period over which drug use can be detected, is easily collected, transported, and stored, and is more difficult to adulterate than urine. The proposed revisions will allow testing hair (1.5 inches long) representing a 90-day sample for pre-employment, random, return-to-duty, or follow-up testing. This method would not be applicable for post-accident.

Oral fluid testing (saliva) is readily available, less invasive and more easily observed than urine specimen collection. Drugs can also be detected in oral fluids within one hour of use. However, current procedures cannot distinguish between actual uses of marijuana and second hand smoke. Thus, a urine specimen test must also be conducted anytime an oral fluid specimen test is positive for marijuana. Oral fluid testing is best suited for pre-employment, reasonable suspicion and post-accident testing.

Sweat testing is conducted by collecting perspiration on sweat wipes or a sweat patch. Sweat collection is a non-invasive procedure, but can result in a rash or skin irritation. Drug use can be detected for as long as the patch remains on the skin. Sweat testing is best used for return-to-duty and follow-up testing, but is not suited for pre-employment, random, reasonable suspicion or post-accident testing.

Comments on the proposed revisions must be made directly to the DHHS by July 12, 2004. Submissions may be made by e-mail to wvogl@samhsa.gov, fax to (301) 443-3031, or mail to 5600 Fishers Lane, Rockwall II, Suite 815, Rockville, Maryland 20857. All submissions must include the agency name and Docket Number **04-7984**.

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 Chapter 7 of the revised *Implementation Guidelines*.

FOR YOUR INFORMATION

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.

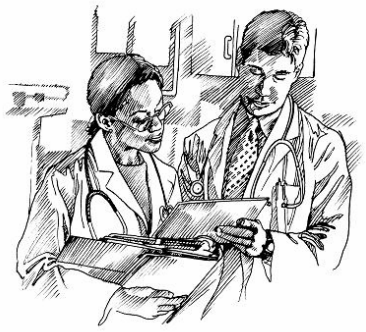
Website location: http://www.workplace.samhsa.gov/ResourceCenter/lablist.htm

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 of the revised *Implementation Guidelines*.

MRO Continuing Ed Deadline Nears

Medical Review Officers (MROs) are required to take a formal training course and pass an examination administered by a nationally recognized MRO professional certification board prior to the performance of any MRO duties under the DOT drug and alcohol testing program. Following the initial training and examination, MROs are required to complete twelve professional development hours of training relevant to MRO functions every three years.



MROs who completed their qualifications training and examination requirements prior to August 1, 2001 must complete their first increment of twelve (12) continuing education credit hours (CEUs) prior to August 1, 2004. Since this deadline is fast approaching, it is highly recommended that you have a dialog with your MRO or third party administrator to ensure that this requirement is being met and that you receive appropriate documentation. MROs that do not meet this requirement will no longer be able to perform services under your FTA drug and alcohol testing program.

List of Certified Labs Continues to Shrink

The list of laboratories certified by the Department of Health and Human Services is published during the first week of each month in the Federal Register. The notice is also available on the Internet at http://workplace.samhsa.gov. Any laboratories whose certification has been suspended or revoked and laboratories that voluntarily withdraw from the program are highlighted.

The list continues to shrink reflecting corporate mergers, consolidations, and voluntary withdrawals. New validity and adulterant testing requirements may result in a further reduction of the number of labs that are willing and certified to perform urine drug testing for federal agencies. Currently, forty-nine laboratories are on the list representing less than half of the number that was certified in the mid-nineties.

Even though the number of labs has diminished, the overall capacity of the remaining labs still exceeds the demand and thus, no employer should experience any adverse consequences due to the reduction. However, employers must remain diligent in their oversight to ensure that the lab that is providing their drug testing services maintains its DHHS certification and is able to provide test results within the regulatory time limitations.

2001 Annual Report Available

Each year all direct recipients of FTA funding are required to collect data on their drug and alcohol testing program for the calendar year and prepare summary reports of the data. If requested, recipients are required to report their data to FTA. For the first time in 2001, FTA used a stratified random sampling system to select the funding recipients that were required to submit their data. The results of the sampling method were summarized and published in the *Drug and Alcohol Testing Results: 2001 Annual Report*. The report includes detailed information on random testing violation rates (sum of positive tests and test refusals), positive post-accident tests, positive test rates for pre-employment, random, post-accident and reasonable suspicion testing categories, and information on return to duty tests.

The report can be obtained online at http://transit-safety.volpe.dot.gov/publications. Print copies of the report can be ordered by contacting Ms. Alison Thompson at thompsona@volpe.dot.gov or faxing your request to (617) 494-2684.

Rx & OTC Medications

Prescription Drugs: Benefits and Risks

Prescription drugs are medications prescribed by a licensed health care professional for a specific medical purpose. These medications are used to treat a wide range of illnesses and injuries, but are controlled due to their potential for abuse or harm. They are meant to be taken under the supervision of a health care professional who can monitor the effect and modify the dosage or discontinue its use as a person's condition warrants. The prescription identifies who the medication is for, the name of the medication, the quantity to be dispensed, instruction on frequency and method of administration, refills, and date. Use of the medication in a manner not specifically defined by the prescription is illegal.

Most individuals realize that prescription medications not taken according to the directions may be addictive, harmful, or deadly. However, many people do not realize that taking prescription medications as directed also involves significant risk. No medication is completely safe. The U.S. Food and Drug Administration (FDA) approval of a drug means that the benefits outweigh the known risks for most people with controlled use. In addition to health risks, use of some prescription medications result in impairment levels equal to or greater than alcohol or illegal drugs. In many instances, the individual may not be able to judge the extent of their own impairment.

To reduce the risks related to using medicines and to get the maximum benefit, the individual must be an active participant in developing his or her treatment plan. The benefit and risk decision is often difficult to make and can only be made in concert with the prescribing health care professional and pharmacist. The following steps are recommended to evaluate the risks and benefits of a prescription medication.

1. **Inform your health care professionals** about your current symptoms, medical history including current treatments and therapies, other prescription, over-the-counter medications, dietary supplements taken, past drug allergies and sensitivities, and safety-sensitive job duties. It is only then, that he/she can develop a plan of care tailored to you.
2. **Ask questions** of your health care professional or pharmacist to help you make best-informed decisions regarding your health care and use of prescription medications.
3. **Learn the facts** about prescribed medications. Specifically ask about active ingredients, proper uses and contraindications, potential side effects, precautions, drug interactions and effects when combined with other medications, food and dietary supplements, if appropriate. Read warning labels and information materials provided by your pharmacy. Read the instructions, check expiration dates, and ask questions if you have any questions.
4. **Balance the benefits and risks**. After you are informed, weigh the benefits with the risks keeping in mind the need to balance the treatment of illnesses and the requirements of performing safety-sensitive functions. Do not avoid essential medical treatment. However, if there is a chance that the medication, illness or treatment will adversely impact your ability to perform your safety-sensitive functions, you should follow your employers' procedures for disqualifying yourself from safety-sensitive duties for the duration of the treatment**.**
5. **Follow the directions**. When you use the medication, maximize the benefits and minimize the risks by following the instructions precisely. Read the label every time you fill your prescription. Be sure you have the right medicine at the right dosage and you understand its use. Read the label every time you use the medicine to be sure it is the right medication for the right person in the right amount, in the right way and the right time. Take the recommended dosage exactly as prescribed and finish all the medicine as directed.
6. **Report Back.** Pay attention to how you feel and notify your health care professional of any problems. **Do not perform any safety-sensitive duty while you are not fit for duty.**

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 home page: www.fta.dot.gov

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

Urine Specimen Collection Procedures Guideline
Substance Abuse Professional Guidelines

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