

#### Summer 2010 Issue 42

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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-second in a series.

#### **Proposed Rule Becomes Final**

On August 16, 2010 the Department of Transportation (DOT) published a final rule in the Federal Register (Vol. 75, No. 157, pages 49850-49864) amending certain provisions of its drug testing procedures defined in 49 CFR Part 40. The final rule which goes into effect on October 1, 2010 makes the DOT rule consistent with most, but not all, of the new procedures/protocols established by the U.S. Department of Health and Human Services.

The preamble to the final rule explains that when the Omnibus Transportation Testing Act of 1991 requires the DOT to follow HHS on specified scientific matters, they do so. When the Act allows the DOT the option of following HHS, the DOT weighs the costs and benefits of following HHS and takes a course of action that best serves the transportation industry. In instances where the Act prohibits the DOT from following HHS, the DOT takes a direction consistent with the Act. Subsequently, the following changes were made to the rule:

- The list of drugs tested for was expanded to include Ecstasy. Initial testing will be conducted for MDMA (Methylenedioxymethamphetamine) and confirmatory testing will be conducted for MDA (Methylenedioxyamphetamine) and MDEA (Methylenedioxyethylamphetamine). Employers that have a list of prohibited drugs in their policy should add MDMA (Ecstasy) to the list. Employers that do not include a list of prohibited drugs, but refer to Part 40, as amended, need not make a change to their policy.
- Test cutoff levels were lowered for Amphetamines and Cocaine. The initial test cutoffs for cocaine metabolites will go from 300 to 150 ng/mL and the confirmation test cutoffs will be lowered from 150 to 100 ng/mL. The initial test cutoff levels for amphetamines will go from 1000 to 500 ng/mL, and the confirmation tests for amphetamines and methampheta-

mines will go from 500 to 250 ng/mL. Employers that include cutoff levels in their policy must revise them to reflect these changes. Employers that do not include cutoff levels in their policy do not need to change their policy if they include by reference 49 CFR Part 40, as amended

- An additional test for 6-Acetylmorphines (6-AM) will be conducted for opiate positives above the initial test cutoff concentration of 2000 ng/mL. The 6-AM test is a definitive marker for heroin use. There is no legitimate medical explanation for 6-AM positive tests. The MRO must confer with the laboratory to determine if there was confirmed morphine below 2000 ng/mL.
- Thirteen definitions were modified or added to harmonize with HHS definitions, and one was removed. See article on page 2 for the new definitions.
- Medical Review Officers (MROs) will no longer be required to obtain twelve hours of continuing education every three years. This requirement was replaced with one that requires requalification including comprehensive re-training that addresses all issues required by Part 40 and passing an examination every five years. The examination must be given by a recognized MRO certification board or subspecialty board for medical practitioners. The training does not have to be conducted by an HHS-approved training organization as long as the MRO meets DOT's requalification training requirements. MROs will be required to complete the new re-qualification training and examination no later than five years from the date of having last met either their qualification training or continuing education requirements. Subsequent re-qualification training will be required every five years thereafter.
- MRO recordkeeping requirements did not change from the five years for non-negative and one year for negatives.

### 6th Annual FTA Drug and Alcohol Program National Conference

The FTA is proud to present the 6<sup>th</sup> Annual FTA Drug and Alcohol Program National Conference! This year's FREE conference will be held in St. Louis, MO April 5 - 7, 2011 at the Hyatt Regency St. Louis at the Arch. This one-of-a-kind FTA Conference offers sessions taught by FTA Drug and Alcohol Program Manager, Jerry Powers, the FTA Drug and Alcohol Program Audit Team, representatives from the Office of the Secretary's Office of Drug and Alcohol Policy and Compliance (ODAPC), and a host of national experts presenting on a wide range of timely subjects. Keep an eye out in early November for "What's New E-mails" and check the website for updates, registration, and additional conference information. <u>http://transit-safety.fta.dot.gov/DrugAndAlcohol</u>.



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## **Definitions Modified and Added**

The following definitions included in 49 CFR Part 40 were modified, added or deleted in the Final Rule published on August 16, 2010. The changes are as follows:

<u>Adulterated Specimen</u> A specimen that has been altered, as evidenced by test results showing either a substance that is not a normal constituent for that type of specimen or showing an abnormal concentration of an endogenous substance.

**<u>Confirmatory Drug Test</u>** A second analytical procedure performed on a different aliquot of the original specimen to identify and quantify the presence of a specific drug or drug metabolite.

**Initial Drug Test (Screening Drug Test)** The test used to differentiate a negative specimen from one that requires further testing for drugs or drug metabolites.

<u>Initial Specimen Validity Test</u> The first test used to determine if a urine specimen is adulterated, diluted, substituted, or invalid. <u>Initial Validity Test</u> Removed

**Invalid Drug Test** The result reported by an HHS-certified laboratory in accordance with the criteria established by HHS Mandatory Guidelines when a positive, negative, adulterated, or substituted result cannot be established for a specific drug or specimen validity test.

**Laboratory** Any U.S. laboratory certified by HHS under the National Laboratory Certification Program as meeting the minimum standards of Subpart C of the HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs; or, in the case of foreign laboratories, a laboratory approved for participation by DOT under this part.

**Limit of Detection (LOD)** The lowest concentration at which a measurand can be identified, but (for quantitative assays) the concentration cannot be accurately calculated.

**Limit of Quantification** For quantitative assays, the lowest concentration at which the identity and concentration of the measurand can be accurately established.

**Negative Result** The result reported by an HHS-certified laboratory to an MRO when a specimen contains no drug or the concentration of the drug is less than the cutoff concentration for the drug or drug class and the specimen is a valid specimen. **Positive Result** The result reported by an HHS-certified laboratory when a specimen contains a drug or drug metabolite equal to or greater than the cutoff concentrations.

**Reconfirmed** The result reported for a split specimen when the second laboratory is able to corroborate the original result reported for the primary specimen.

**<u>Rejected for Testing</u>** The result reported by an HHS-certified laboratory when no tests are performed for a specimen because of a fatal flaw or a correctable flaw that is not corrected.

**Split Specimen Collection** A collection in which the urine collected is divided into two separate specimen bottles, the primary specimen (Bottle A) and the split specimen (Bottle B).

### Pre-Employment Drug Test Should Occur Before Medical Exam

Some employers send applicants for a fitness-for-duty medical examination on the same day and possibly at the same time they send applicants for their pre-employment drug test. If this is the case, the drug test should be conducted first to avoid an insufficient specimen resulting from a urine sample collected as part of the medical examination. The medical examination should be completed after the DOT-regulated drug test has been completed.

If the drug test requires a wait time due to insufficient volume, the medical examination cannot be initiated during the wait period, but must be delayed until the collection is completed in its entirety. If there is excess urine after both specimen bottles have been appropriately filled and sealed, the collector may use the excess to conduct clinical tests (e.g., protein, glucose) for a physical examination required by a DOT agency regulation (§40.71)

## Date For New ATF Extended

The Alcohol Test Form (ATF) was updated to include the new DOT address, new DOT form numbers, and additional instructions on the reverse side of page

3 regarding the process for attaching test results with the use of tamper evident tape. The form also includes the updated Paperwork Reduction Act Burden Statement. In order to allow regulated employers and their service agents sufficient time to use up existing supplies of the old forms, a final rule was published in the Federal Register (Vol. 75, No. 127, pages 38422 – 38423) on July 2, 2010 that changed the mandatory start date for use of the new forms to January 1, 2011. Old or new forms can be used up until that date, but after, only the new forms will be allowed.



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#### **IITFs Will Not Be Allowed**

The Notice of Proposed Rulemaking (NPRM) published on February 4, 2010 proposed the introduction of Instrumented Initial Testing Facilities (IITFs) in the Department of Transportation (DOT) testing program for

use by covered employers to conduct initial drug screen tests. As proposed, the IITFs would have been limited to providing test results to employers that were negative, negative dilute, and specimens rejected for testing. All other non-negative tests would have been forwarded to an HHS-certified laboratory for additional testing.

Upon further analysis, the DOT concluded that the Omnibus Transportation Testing Act of 1991 actually prohibits the Department from following HHS on the issue of IITFs. The Act requires that all laboratories involved in the controlled substances testing of any individual under DOT authority "shall have the capability and facility, at such laboratory, of performing screening and confirmation tests." Subsequently, the use of IITFs will not be allowed for DOT testing. The rule remains as written in regards to the requirement to use HHS-certified laboratories for both initial screen and confirmatory testing.

#### **Random Test Results Remain Stable**

The preliminary test results of the Federal Transit Administration's (FTA) Drug and Alcohol Testing Program for Calendar Year 2009

have been generated. The results indicate that the random positive drug test rate remained stable. The 2010 positive drug test rate was 0.81. The rate was at its highest in 1995 at 1.76 percent of all random drug tests and declined each year to a low of 0.79 percent in 2005. Since then, the rate has stayed virtually the same with only a 0.03 percent fluctuation in the results. The 2009 alcohol violation rate returned to its all time low of 0.11 percent following a slight increase the previous two years.

The positive drug test rate is calculated by adding the number of verified positive results plus the number of refusal results divided by the number of test results. For alcohol tests, the violation rate is calculated by adding the number of confirmation tests with results of 0.04 or greater plus the number of refusal results divided by the number of screening test results. In 2009, test result information was collected from 3,264 employers covering 280,731 safety-sensitive employees. Of the 100,263 random drug tests performed, 723 had verified positive results and 87 were test refusals. Of the 42,988 random alcohol screen tests, 35 had confirmation tests results of 0.04 or greater and 13 were test refusals.





Drug & Alcohol

fulation Updates



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# OUR INFORMATION

#### **Confusion Over Volunteers** Clarified

The Federal Transit Administration has become aware of some confusion in the transit industry

regarding how the regulation applies to volunteers. Some of the confusion is due in part to the definition of what constitutes a volunteer and the safety-sensitive duties they perform. To clarify:

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All volunteers who perform safety-sensitive duties for an FTA covered employer are exempt from the FTA drug and alcohol testing requirements, except for those volunteers who are required to operate a vehicle that requires a Commercial Driver's License (CDL).

Volunteers are defined as non-employees who perform a service as a charitable act without the expectation of receiving

## **Penalty Authority**

benefit. These individuals are exempt from the regulation. If an employer chooses to include safety-sensitive volunteers in their program, they may do so under their own authority. Those individuals who perform safety-sensitive functions as a charitable service, but do so in return for some benefit (i.e., workfare, community service as an alternative to a criminal sentence, academic credit, or payment by another agency) are not considered volunteers and are covered by the regulation.

Volunteers who receive mileage reimbursement only (consistent with federal mileage reimbursement rates) are not covered. However, volunteers who receive remuneration in excess of their personal expenses incurred while performing the volunteer service (i.e., stipend, excess mileage rates, gift cards) are considered a covered employee and must be included in the program.

Senate Bill Promises to Give FTA Civil The Bill before the Senate and House of Representatives known as the "Public Transportation Safety Act of 2010" was created to establish a national safety plan for public transportation. This comprehensive safety Bill was created because the sponsors believed a "greater investment by the Fed-

eral Government in transit safety is necessary to better protect public transportation passengers and keep the economy of the United States operating efficiently through the safe movement of goods and people." This concern was compounded by the fact that the Federal Transit Administration (FTA) lacks the authority to implement and enforce national public transportation safety standards.

The House Bill is still in committee, but the Senate Bill is out of committee and will be scheduled for a full Senate vote soon. This Senate Bill includes amendments to the Public Transportation Safety Program (Section 5329), Transit Asset Management (Section 5326), National Transit Database (Section 5335), and additional safety provisions of Title 49. Of relevance to the FTA drug and alcohol testing program is Section 6(d) which states that the Federal Transit Administration "shall establish and implement an enforcement program that includes the imposition of penalties for failure to comply" with alcohol and controlled substances testing. This provision, if passed, will provide FTA with an enforcement tool against non-compliant service agents such as collection sites and Medical Review Officers (MROs). These civil penalties would be in addition to or instead of any Public Interest Exclusion (PIE) as a means of achieving service agent compliance. For more information about this Bill, go to http://thomas.loc.gov/home/gpoxmlc111/s3638\_pcs.xml.

#### **Clandestine Collections Reveal Problems** At Collection Sites

Federal Transit Administration (FTA) drug and alcohol auditors have conducted ninety-one clandestine reviews of collection sites to date. The reviews were performed without the collection sites' knowledge as auditors presented themselves as transit system employees. The reviews were distributed throughout all regions of the country and included both local and national agencies.

Of the collection sites reviewed, ninety-eight percent (98%) had at least one finding. Over half had 25 findings or more. Among the most frequently identified errors cited in the reviews are as follows:

The collector completed Step 4 of the Custody and Control

Form (CCF) prematurely.

- Privacy enclosure was not secured properly.
- The collector did not write the date on the tamper-evident bottle seals.
- The collector did not explain the basic collection procedures or show the instructions on the back of the CCF.
- The privacy enclosure was not inspected by the collector.
- The donor did not complete Step 5 on Copy 2 of the CCF.
- The donor was not required to empty his/her pockets.
- Bluing agent was not put into the toilet.
- The donor was not required to wash his or her hands prior to providing the specimen.
- The donor placed initials on the seal while still attached to the CCF.



For Your Information

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If an employee provides personal information when being interviewed by a Medical Review Officer (MRO) following a laboratory non-negative test result, does the MRO include this information in the official record, and will this information be reported to the employer?

> Medical Review Officers (MROs) should record information that is specific to the issue at hand or that may have information should not be included in the official record. MROs must draw on their training as physicians and

MROs to determine what information is relevant to the verification process or transportation safety.

#### Are there any potential medical explanations for testing positive for Ecstasy? 6-AM?

No. Like PCP there is no valid medical explanation for testing positive for 6-AM, MDMA, MDA or MEDEA. §40.151(g) clearly instructs MROs to "not accept an assertion that there is a legitimate medical explanation for the presence of PCP, 6-AM, MDMA, MDA, or MDEA in a specimen." Do collectors need to obtain prior approval from a collection site supervisor before performing a directly observed collection?



an impact upon safety. Other sensitive, unrelated personal of the night. Requiring supervisor approval in these situations would delay the process unnecessarily. Collectors must be trained on direct observation procedures; the DOT has provided detailed guidance and technical assistance resources to assist the collector.

Who determines if an employee has refused a test?

The Medical Review Officer makes the determination in instances where the specimen is verified as adulterated or substituted (§40.355(i)), or when an individual is unable to provide a sufficient amount of urine for the drug test (shy bladder) without an adequate medical explanation (§40.193(d)

(2)). The Collector and the Designated Employer Representative (DER) make the determination in all other cases when the individual fails to follow the required procedures to provide the specimen (§40.191(a)). For a detailed listing refer to the regulation or Issue 37, page 3 of the FTA Drug and Alcohol Regulation Updates.

## COMMON UDIT FINDINGS

#### Delaying Screen Test to Allow Mouth Alcohol to Dissipate Not Allowed

An employee who recently used breath spray, mouthwash, or any other substance that would result in accumulation of alcohol in the mouth could have an artificially high reading on an alcohol screening device whether it is a breath or saliva testing device. The regulation (§40.251) takes this into consideration by requiring that the confirmation test be conducted at least fifteen minutes, but not more than thirty minutes, following the screen test. This minimum time allowance is more than sufficient to allow any residual amount of alcohol left in the mouth to dissipate prior to the confirmation test.

It has come to the attention of FTA auditors on recent audits that some Breath Alcohol Technicians have been delaying the initiation of an alcohol test for fifteen minutes to allow any residual alcohol present in the mouth to dissipate prior to the initial screen test. This is incorrect. The alcohol test is to be conducted without undue delay. The added wait time prior to the initiation of the test is in violation of the rule and is unnecessary. If the employee had any residual mouth alcohol, it would dissipate prior to the confirmation test. Since the confirmation test is the test of record, the result of the screen test is not relevant.



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# **DTC MEDICATIONS**

#### Diabetes Mellitus (commonly **Driving and Diabetes**

referred to as diabetes) is a

group of diseases characterized by high blood glucose, or sugar, levels that result from the body's inability to produce and/or use insulin. Diabetes affects an estimated 23.6 million people in the United States, or 7.8 percent of the population. Of the almost 24 million individuals with diabetes, only an estimated 18 million have been diagnosed. Another 57 million people are considered "pre-diabetic." About 1.6

million people aged 20 or older are diagnosed with diabetes each year; and, diabetes is the seventh leading cause of death in the United States. (Source: American Diabetes Association).

Diabetes affects the way the body uses and produces insulin and glucose (blood sugar), resulting in hyperglycemia (too high blood sugar) or hypoglycemia (too low). Short term

Transit systems must be concerned with the overall health of their employees, as well as the medications they use and the impact on transit safety. As is the case with most medications, diabetes medications come with a variety of side effects, some more serious than others. In the case of side effects which may impair driving, all of the medications listed on this page have the ability, either by themselves or taken in concert with other diabetes medications, to cause

Commonly Prescribed Diabetes Medications	
Trade Name	Generic Name
Actoplus Met	pioglitazone/metformin
Actos	pioglitazone
Amaryl	glimepiride
Avandia	rosiglitazone
Byetta	exenatide
Diabeta, Micronase, Glynase	glyburide
Glucophage, Fortamet, Riomet	metformin
Glucotrol	glipizide
Glyset	miglitol
Prandin	repaglinide
Precose	acarbose
Starlix	nateglinide

Hypoglycemia. The symptoms of Hypoglycemia include, but are not limited to blurred vision, lightheadedness, dizziness, shakiness, mental disorientation, and anxiety, all of which pose major safety concerns while driving. For this reason, safety-sensitive employees should not perform any safety-sensitive function while the possibility exists for impairment as a result of either their diabetes condition or the

diabetes effects include, but are not limited to, sleepiness; dizziness; shakiness; mental confusion; blurred vision; loss of consciousness, and/or seizures. Medications, insulin and non-insulin products, are used to control, not cure, diabetes, but come with their own side effects. Inserted is a list of the most common non-insulin diabetes medications prescribed today.

Note: Commercial Driver's License regulations specifically address diabetes and insulin-dependent diabetics. For more information, please see Federal Register Vol. 68, page 52331, September 3, 2003; the Federal Motor Carrier Safety Administration website, www.fmcsa.dot.gov, and/or the American Diabetes Association website, <u>www.diabetes.org</u>, for more information on the CDL diabetes exemption program.

medications being taken to control it.

There are many resources available on the diagnosis and medications used to treat diabetes that can be incorporated into your safety awareness and training programs. A few examples include the American Diabetes Association, www.diabetes.org, which is an excellent source of information as is the National Diabetes Information Clearinghouse, www.diabetes.niddk.nih.gov. The National Highway and Traffic Safety Administration produced an excellent brochure entitled "Driving when You Have Diabetes," DOT HS809684, November 2003. Finally, the National Institute on Aging produces a series of "Age Pages" on a variety of conditions including, diabetes. Go to http:// www.nia.nih.gov/HealthInformation/Publications/ diabetes.htm.



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# **Seminars**

The FTA is offering a free one-day training seminar in Houston, TX on November FTA Free One-Day Training 9, 2010 and is working to schedule additional seminars. These one-day seminars are designed to provide essential facts and information to facilitate employers' compliance with DOT's 49 CFR Part 40 and FTA's 49 CFR Part 655. They are taught by actual FTA audit team members.

> The audience for the seminars is generally transit agency drug and alcohol program managers, human resource managers, safety managers, and third party contractors for the transit substance abuse programs. Please visit http://transit-safety.fta.dot.gov/Training/new/default.aspx for the calendar of events, course description, and registration.

### **Reasonable Suspicion** Classes Offered

The Transportation Safety Institute (TSI) is offering two one-day classes on Reasonable Suspicion for Supervisors. The class will be offered on November 19, 2010 in Savannah, Georgia and repeated on April 22, 1011 in Salem, Oregon. The cost of the class is \$30. To register, go to the TSI website at <u>www.tsi.dot.gov/</u> and

enter Class ID #FT00546.

The class focuses on the specific training requirements for supervisors who will be making the determination of when to administer reasonable suspicion drug and/or alcohol tests. Participants will learn to identify the signs and symptoms and physical, behavioral, speech, and performance indicators of probable drug use and alcohol misuse. They will also learn how to make a fair and reliable reasonable suspicion drug and alcohol test referral.

FTA Drug and Alcohol MIS Project Office: Phone: (617) 494-6336 Email: fta.damis@dot.gov FTA home page: http://www.fta.dot.gov Center for Substance Abuse Prevention: http://prevention.samhsa.gov DHHS-Certified Laboratories: http://www.workplace.samhsa.gov/DrugTesting/Level 1 Pages/ 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 **Collection Site Security and Integrity Poster DOT Direct Observation Instructions Sheet** DOT's Ten Steps Video **MIS Data Collection Form and Instructions** 

**Technical Assistance** 

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## FTA Drug & Alcohol FTA Drug & Alcohol Regulation Updates Regulation Updates Produced by: FTA—Office of Safety and Security

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; Pages 8526-8528: Permits New ASD; Pages 8528-8529; New ATF and MIS Forms

August 16, 2010 Federal Register Vol 75, No. 37, Pages 49850-49864; Addition of Ecstasy, Lowering Cutoff Levels, MRO Qualifications.

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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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