#### FTA Drug and Alcohol REGULATION UPDATES

Winter 2012

ISSUE 47

#### 7th Annual FTA Drug and Alcohol Program National Conference in Miami

The Federal Transit Administration (FTA) is hosting the 7th Annual Drug and Alcohol Program National Conference on April 10 - 12, 2012. This FREE three-day conference will provide attendees with strong knowledge of 49 CFR Part 40 (Procedures for Transportation Workplace Drug and Alcohol Testing Programs) and 49 CFR Part 655 (Prevention of Alcohol Misuse and Prohibited Drug Use in Transit Operators). This meeting will be invaluable for those who have been in the industry for a long time, as well as those that have been in the industry for



a shorter period as sessions are tailored for both groups.

Speakers and industry experts will be from the FTA, the Office of the Secretary's Office of Drug and Alcohol Policy and Compliance (ODAPC), FTA Drug and Alcohol Auditors, FTA Drug and Alcohol Program Staff, the Transportation Safety Institute (TSI), the Federal Motor Carrier Safety Administration (FMCSA), Medical Review Officers (MROs), Substance Abuse Professionals (SAPs), Urine Collectors, Breath Alcohol Technicians (BATs), and Third Party Administrators (TPAs). (Continued on page 2)

#### Five Practices Mistaken for Regulations

In the Drug and Alcohol Testing Program, there is no shortage of regulatory advice and requirements being offered and imposed from auditors, consultants, colleagues, vendors, and local or state regulators. Many of the issues that are taken as given are based on regulations, and can be read clearly in either Part 40 or Part 655. There is, however, a tendency to accept some industry standards as regulation, many of which have worked their way deeply into the collective operating assumptions of transit agencies and their vendors.

Some practices that have been assumed as regulations are not required at all, and appear nowhere in Part 40 or Part 655. The following are 5 practices that are commonly mistaken for regulations.

#### 1 All cabinetry and areas of concealment in a collection site enclosure must be removed or locked.

Part 40.43 lists the steps for securing a collection site enclosure:

- (5) Tape or otherwise secure shut any movable toilet tank, or put bluing in the tank;
- (6) Ensure that undetected access (e.g., through a door not in your view) is not possible;
- (7) Secure areas and items (e.g., ledges, trash receptacles, paper towel holders, under-sink areas) that appear suitable for concealing contaminants. (Continued on page 3)

#### IN THIS ISSUE

- 2 Automatic Sinks and Toilets Pose Challenge
- 3 Five Practices That Are Mistaken for Regulations
- **4** DAMIS Annual Reports due 3/15
- 5 New Questions in the DAPM Questionnaire
- 8 Six Changes That Will Immediately Improve Your Drug and Alcohol Program
- 10 Transit Safety Institute Training Schedule



. tment of Transportation Federal Tran it Ad i i tration

#### 7th Annual FTA National Conference in Miami

(Continued from page 1)

This year there will be a resource room with the following: FTA Drug and Alcohol Policy Review, Rx/OTC Policy Best Practices Review, EBT Demonstrations, and Alcohol Saliva Test Demonstrations, examples of various adulterants, substitutions and ways to beat a test and FTA Drug and Alcohol free publications.

For more information, go to http://transit-safety.volpe.dot.gov/DrugAndAlcohol/Training/NatConf/2012/.

#### **New Sessions This Year**

- Modernizing your FTA Compliant Training Program
- You Can't Fool Us! Catching the Cheaters
- The Grantee/Contractor Relationship
- The Most Common Audit Findings
- Municipalities or Agencies Dispersing D&A Functions
- Collection Site Proficiencies
- The DOT-Qualified Substance Abuse Professional (SAP): We Have the Smack
- HHS-Certified Labs and the DOT Program
- Why is March 15th Important? MIS Reporting & Website Resources

#### Automatic Sinks and Toilets Pose Challenge

All urine specimens collected under Federal Transit Administration (FTA) authority must be collected according to the requirements established in 49 CFR Part 40 and further explained in the Urine Specimen Collection Guidelines published by the Office of the Secretary's Office of Drug and Alcohol Policy and Compliance (ODAPC) revised October 1, 2010. The collection site must provide a privacy enclosure for urination and a water source for hand washing, which if practical, should be outside the privacy enclosure. All water sources within the privacy enclosure must be secure, turned off, or bluing agent added to ensure that the donor does not have access to clear water to potentially dilute the specimen.

The collector must instruct the donor not to flush the toilet to ensure that clear water is not introduced into the bowl. If a donor flushes the toilet anyway, no corrective action or recollection is needed. The collector should write 'the donor flushed the toilet' in the "Remarks" line in Step 2 on the Chain of Custody and Control Form (CCF)



(© iStockPhoto/John Shepherd)

## "If a donor flushes the toilet anyway, no corrective action or recollection is needed."

and proceed with the collection.

To guard against inadvertent flushing, however, collectors are encouraged to post a sign in the privacy enclosure

instructing the donor not to flush. In addition, collectors are encouraged to remove the toilet handle, tape it in place, or otherwise secure the handle with tamper-evident tape. Likewise, the tank lid should be secured to prohibit access to tank water and to eliminate the tank as a potential site for storing adulterants.

As new or remodeled restroom facilities are being utilized for collection sites, automatic flushing toilets and sinks have posed a challenge. In some cases, simply taping off the sensor with dark tamper evident tape disengages the automatic flush mechanism of the toilet or the automatic faucet of the sink. In other cases, taping off the sensor engages the mechanism resulting in ongoing and unpredictable flushing and water flow from the sink. In these cases, an alternative method of securing the water flow (i.e., turning off valves) must be implemented.

Employers or collection sites considering installing automatic sinks or toilets in a privacy enclosure used for specimen collection are advised to take this issue into consideration.

#### Five Practices That Are Mistaken for Regulations

(Continued from page 1)

The regulations require that collectors "secure" the enclosure before each collection. One collection site recently audited had a storage cabinet in the enclosure. The collector told the auditors that before each collection, the cabinet doors are opened, and left open during and after the collection. A visual inspection by the collector before and after served as an acceptable method for securement. While the quickest and easiest method for securement is locking and sealing, it is not specifically required, and collection sites may use other creative techniques to meet the intent and letter of the regulation.

## "Some practices assumed as regulations are not required at all."

The concealment of contaminants, masking devices, or substitution containers is a primary concern, as is eliminating areas to hide these items.

#### 2 Tamper-evident tape must be used on ceiling tiles, and on toilet tanks in a collection site enclosure.

This is related to the regulation above. Auditors often recommend or require securement of ceiling tiles, but it is not the only option. A toilet tank may be secured using heavy packing tape or other method, including a locking post through the top of the lid. Again, the intended outcome is securement either through physical prevention of access (packing tape, adhesives, etc.) or through tamper-

evident techniques (evidence tape, etc.). If a collection site can show that they have devised a method or protocol which provides adequate securement of all realistic areas to conceal materials, it should be enacted. Auditors can require that changes be made to reach compliance, but the industry has proven that there are many methods to achieve the desired outcome.

#### A collection site must provide 40 ounces of water for employees during a shybladder waiting period.

Part 40.193(b) (2) actually only requires "fluid" be provided, and does not specify the type:

"Urge the employee to drink up to 40 ounces of fluid, distributed reasonably through a period of up to three hours, or until the individual has provided a sufficient urine specimen, whichever occurs first. It is not a refusal to test if the employee declines to drink. Document on the Remarks line of the CCF (Step 2), and inform the employee of, the time at which the three-hour period begins and ends."

Coffee, soda, juice, or water are all acceptable beverages (fluids) to offer the employee.

#### 4 A supervisor must escort an employee to the collection site.

The FTA has always supported this practice as a good management and safety measure, but the regulations certainly do not require it. For many small transit systems, this would make daily operations impossible, and the testing program would be unable to function in harmony with basic transit service. Larger systems may have the personnel available to escort and transport the employee to the collec-

tion site, some opting to escort only for post-accident and reasonable suspicion tests. The choice belongs to the employer, and is not addressed in the regulations.

#### 5 After being notified of a random test, an employee must report to the collection site within 30 minutes.

Part 655.45(h) only requires that "Each employer shall require that each covered employee who is notified of selection for random drug or random alcohol testing proceed to the test site immediately."

The regulations say "immediately," and give no specific time limit. Some transit systems have enacted their own time limits (10, 30, 60 minutes), but even these may not be compliant. At the time of notification, the employee must proceed immediately to the collection site and the realistic travel time between where they are physically at that moment and the collection site should be stated as their time limit. A standing deadline of 30 minutes is worthless if the employee is notified when they are 10 minutes away from a collection site. Alternatively, it is unfair to give an employee 60 minutes to reach a collection site if they are well over an hour away, taking into account distance and traffic or weather delays.

At the time of notification, the employee should be given a location-specific time limit only, and drug and alcohol program policies should remove any mention of a standing time limit if the conditions do not warrant it.

Always read the regulations closely, or call the FTA Drug and Alcohol Project Office at (617) 494-6336 if you doubt the origin or claim of any requirement. Since the required end result is compliance, there can be several methods to achieve it.

#### Drug and Alcohol Management Information System (DAMIS) 2011 Annual Reports **due March 15th**

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

§655.72 Reporting of results in a management information system

- (a) Each recipient shall annually prepare and maintain a summary of the results of its anti-drug and alcohol misuse testing programs performed under this part during the previous calendar year.
- **(b)** When requested by FTA, each recipient shall submit to FTA's Office of Safety and Security, or its designated agent, by March 15, a report covering the previous calendar year (January 1 through December 31) summarizing the results of its anti-drug and alcohol misuse programs
- **(c)** Each recipient shall be responsible for ensuring the accuracy and timeliness of each report submitted by an employer, contractor, consortium or joint enterprise or by a third party service provider acting on the recipient's or employer's behalf.

If you are a transit entity or state DOT that receives FTA funding, you must prepare and maintain a summary of your annual drug and alcohol test results and you should have received a notification letter directing you to submit your 2011 results. The notification letter is part of the reporting packages sent out in late December. The packages include your user name and password, instructions on reporting, a copy of the new MIS form, and information on how to download

your contractors'/subreceipients' user names and passwords. If you are an FTA direct recipient and have not received your reporting package, please contact the FTA Drug and Alcohol Project Office.

There are some common misconceptions that many reporters make so as a reminder:

- Your user name and password changes every year. Using last year's user name and password will not enable you to report online.
- You must download your contractors'/subrecipients' user names and passwords and provide these to them.
   Contractors cannot contact the FTA Drug and Alcohol Project office to obtain them.
- The FTA Drug and Alcohol Project
   Office uses last year's information
   submissions to create the list of
   contractors/subrecipients. If this list

has changed since the 2010 reporting year, reporters must notify The FTA Drug and Alcohol Project Office to update and add or delete contractors/subrecipients.

- Direct recipients are responsible for reviewing and accepting their contractors/subrecipients data.
   Until this is done, your transit agency or state DOT MIS requirement is considered incomplete.
- To report online (the DOT-preferred method), go to http://damis.dot.gov.
   If you have any questions, please

email The FTA Drug and Alcohol Project Office at fta.damis@dot.gov or call (617) 494-6336. As the March 15th deadline approaches the volume of calls increases. Please leave a voicemail if no one is available to pick up the phone. Your patience is deeply appreciated.

# OMB No. 2105-0529 Form DOT F 1385 (Rev. 5/2008)

If you are a direct recipient of FTA funding, you should have received a notification letter and MIS reporting package. If you didn't, contact the FTA Drug and Alcohol Project Office at **(617) 494-6336.** 

#### New Questions in the Drug and Alcohol Program Manager (DAPM) Questionnaire

The FTA has recently revised the interview questions used in the Drug and Alcohol Compliance Audit Program. In the revision, there is more focus on the transit system's knowledge of, and procedures for, prescription and over-the-counter medication use.

For instance, the FTA expanded the questions for the DAPM about the transit system's Prescription and Over-the-Counter (Rx/OTC) Medication Procedures.

The previous set of questions, introduced in 2002, only asked the DAPM whether the transit system had any policies and procedures concerning prescription and OTC drugs and, if so, when those policies were formulated.

### "The questions will extend FTA's knowledge of how transit systems gather data."

Since then, the FTA has published and revised the Prescription and Overthe-Counter Medications Tool Kit (April, 2011 Version) and conducted two surveys of transit systems (see Issue 40 and other previous newsletters). The revised DAPM interview questions will extend FTA's knowledge of how transit systems gather data about prescription

and over-the-counter medications used by employees and whether systems consider the possible impact of these drugs during accident investigations. The new questions are in the text box. They are non-regulatory, as the introduction indicates, and for information-gathering only.

FINALLY, AND PURELY AS A MATTER OF INFORMATION GATHERING AND NOT REGULATORY COMPLIANCE, WOULD LIKE TO ASK A FEW QUESTIONS ABOUT ANY POLICIES AND PROCEDURES YOUR SYSTEM MAY HAVE CONCERNING THE USE OF OVER-THE-COUNTER AND PRESCRIPTION DRUGS BY SAFETY-SENSITIVE EMPLOYEES.

- **80.** Do you use the services of a medical practitioner to determine employee fitness for duty while taking a prescription medication?
- 81. Do you require safety-sensitive employees to report all Rx/OTC medication use?
- **82.** If so, is the medical practitioner the prescribing physician, transit system physician, CDL physician, or other?
- **83.** Do you use the services of a medical practitioner to determine employee fitness for duty while taking an over-the-counter medication?
- **84.** If so, is the medical practitioner the employee's physician, transit system physician, CDL physician, pharmacist or other?
- **85.** Are the employee's essential job functions communicated to the prescribing physician?
- **86.** Do you address the use of Rx/OTC medication with an employee during an accident investigation procedure? If yes, do you address Rx/OTC as part of your standard accident/investigation procedure or only when the circumstances of the accident point toward Rx/OTC as a potential contributing factor?
- 87. If Rx/OTC medications were determined to have had a causal or contributing effect on an accident, how was the determination made (i.e., employee self-report, testing in addition to the required DOT test, fitness for duty medical evaluation, review of employee's medical records on file, hospital report, police report, etc.)?

#### MRO Must Maintain Originals of CCFs

The drug testing industry has experienced some confusion regarding which Medical Review Officer (MRO) documents must be maintained in paper originals and which can be maintained in electronic format. With improvements

in technology and electronic data management, Third Party Administrators (TPAs) and MROs are attempting to increase efficiency by migrating as much of the record keeping and reporting processes as possible to paperless systems where all documents are scanned into an electronic format. Even though many of these efforts should be applauded, the regulation does not allow for a completely paperless system. (Continued on page 7)

#### Ensuring a Truly Random Testing Program

One of the key features of FTA's substance abuse management regulation, "Prevention of Alcohol Misuse and Prohibited Drug Use in Transit Operations," is the requirement to deter the use of controlled substances and the misuse of alcohol through the application of a robust random testing program. The FTA has long held that the best way to achieve and maintain this deterrent is through ensuring that employees are truly surprised when selected to submit to random drug and alcohol testing.

While this surprise will indeed detect the use of a prohibited substance, the real goal is to deter use by keeping employees "on their toes." Accordingly, FTA requires in section 655.45(g) that tests are "unannounced and unpredictable," and that the dates for administering random tests are spread reasonably throughout the calendar year. This section goes on to state that random testing "must be conducted at all times of day when safety-sensitive functions are performed." FTA reiterated in a May 1998 legal interpretation that "employees performing safety-sensitive functions after normal business hours or on the weekends remain subject to random testing."

The idea underpinning this "reasonable spread" of testing is that an employee must not be able to predict through past experience the likelihood of a future testing event. If a transit system or its third-party administrator performs random selections and testing on a quarterly basis at the very beginning of the quarter, then the tested employees — and probably all employees — will expect that three months will pass before another "random" testing event takes place. To combat this awareness and expectation, FTA requires that the employee perceives

"The FTA has long held that the best way to achieve and maintain this deterrent is through ensuring that employees are truly surprised when selected to submit to random drug and alcohol testing."

the events to be "random," in nature, which is to say, unpredictable. While the transit system may certainly perform its random testing selections on a fixed quarterly basis (for example, on January 1st, April 1st, July 1st, and October 1st), the testing itself must be spread out so that employees do not recognize any patterns of testing throughout the year, work-week, or day.

Given this goal, an important consideration when administering a strongly deterrent random testing program is the selection process itself. Section 655.45(e) requires that the selection of employees for random testing be made by a scientifically valid method (computer program, random number table, etc.), and states that under the selection process being used, "each covered employee shall have an equal chance of being tested each time selections are made." The phrase "each time selections are made" is critical in understanding the key characteristic of a truly random selection process.

The traditional understanding of this phrase is that if an employee is selected for testing in the first quarter, the employee is not "let off the hook" for the remainder of the year, but instead will be in the eligible selection pool in all future quarters. That is to say, he will be eligible

for testing "each time" selections are made. This employee may be selected in the first quarter and again in the second, third, and fourth quarters. Program administrators have probably received complaints from these "lucky" employees before.

While FTA and its drug and alcohol program auditors have long allowed this practice (and still do), it is not a technically accurate interpretation of the phrase "each time selections are made." In a truly random process, each selection from the pool (i.e., each name drawn) is a unique "selection time." Accordingly, the pool of eligible names from which random tests are drawn should be the same for every individual pick. This means, of course, that an employee could come up for testing more than once in the same selection period.

Administering a random testing program using this technique gives the program manager a very powerful tool in supporting the deterrent effect of surprise testing. An employee selected in January and tested in February could no longer guess that it will be at least April before they are tested again. Instead, the program manager might send the employee for testing again the next day, which would be quite a surprise indeed.

#### Random Testing for Small Transit Systems

For rural or small transit systems with lower numbers of safety-sensitive employees, achieving unpredictability in the random testing program can be difficult. For example, a small transit system with 12 full-time safety-sensitive employees would be required to test a minimum of 4 employees per year. It is reasonable to assume that selections would likely be performed quarterly, meaning that each quarter only one employee would be selected. In this scenario, despite the transit system varying the times of day, the days of the week, and the date within the selection period for which the employee is sent for random testing, a glaring problem quickly emerges. With one test expected per quarter, employees may not know when the test will occur, but once it does, they are nearly certain that another test will not be ordered until the next quarter, eliminating the element of deterrence.

To solve the predictability of testing with very small random programs, a transit system may want to take randomization a step further, by randomizing their testing rate. This would mean that once a year, or even once per draw period, the rate at which selections are conducted will be randomly varied. For example, the DER may choose to test at 25% for the first quarter, 50% the next quarter, and 25% for the remaining two quarters. The result will be only one additional test, but the effect will be to let employees know that random testing may happen at an increased rate without their knowing. In terms of affordability, even testing 75 or 100% for one quarter will be easily achievable because the overall employee base is comparatively small. While 100% sounds shocking at first, for a small transit system it may mean the

addition of only 6 to 8 tests per year, which is an affordable measure for ensuring that the random program is truly unpredictable.

Since the goal of the random program is both detection and deterrence of drug use and alcohol misuse, each employee should have a reasonable expectation that they may be selected for random testing anytime they are performing safety-sensitive duties. Randomizing (or strategically altering) your random testing rate each selection period may be an effective way of drastically improving your random testing program.



Rural transits systems face unique challenges in maintaining a compliant random testing program. (© iStockPhoto/Jeff T. Green)

#### MRO Must Maintain Originals of CCFs

(Continued from page 5)

49 CFR Part 40.163 (e) states that MROs must retain signed or stamped and dated copies of Copy 2 of the Chain of Custody and Control Forms (CCF) in their records. If the MRO does not use Copy 2 for reporting results, the MRO must maintain a copy of the signed or stamped and dated letter in addition to the signed or stamped and dated Copy 2. Similarly, if the electronic data file is used to report negatives, the MRO must maintain a

retrievable copy of that report in a format suitable for inspection and auditing by a DOT representative.

Copies of the CCFs may be scanned and stored electronically, however the original hard-copies must also be retained in accordance with the timeframes set forth in the regulation to allow for inspections and audits. In general, all documents that require the MRO's original signature, stamp or initial must be kept in paper format. Scanned originals of the CCFs

should not be shredded or destroyed until after the specified record retention timelines have expired.

All records, hard-copy and electronic, must be easily and quickly accessible, legible, formatted and stored in a well-organized manner. If electronic records (i.e., scanned documents) are not legible or accessible, the service agency must convert them to printed documentation within two days of a request by a U.S. Department of Transportation (DOT) representative.

#### Six Changes That Will Immediately Improve Your Drug and Alcohol Program

Every transit drug and alcohol program will experience change this year. Funding levels will go up or down, personnel will come and go, vendor performance will improve or deteriorate, and most commonly, employee rosters will grow and shrink. With so many changes in the testing program, a steady approach is important to maintain, and every Designated Employer Representative (DER) and Drug and Alcohol Program Manager (DAPM) should be thinking about improving their program efficiently and effectively.

The FTA drug and alcohol testing program is a robust safety layer which has immediate real-world impact and consequences, requiring vigilant management, consistent application, and full participation. To immediately improve your program, the following steps may have the highest possible impact.

#### 1 Review your employee training programs.

Across the country, recent audits are finding that training programs are either outdated, poorly attended, or non-existent. New employees who perform safety-sensitive duties must be given 60 minutes of training on the effects and consequences of prohibited drug use on personal health, safety, and the work environment, and on the signs and symptoms that may indicate prohibited drug use (655.14(b)(1)).

#### 2 Review your supervisor training programs.

Thorough training for reasonable suspicion evaluations and determinations will provide your transit system with a



These changes will help drug and alcohol programs improve efficiency and effectiveness. (© iStockPhoto/Jesus Jauregui)

proactive safety system. Proper training consists of 60 minutes on the signs and symptoms of drug use and 60 minutes on the signs and symptoms of alcohol misuse (655.14(b)(2)), for a minimum total of two hours.

#### 3 Visit your collection site.

Collection sites are most often the weakest link in the entire program. Have the collection site walk you through the process step-by-step, and ask as many questions as possible. Compare what the collections site says to what your records say, and download the FTA collection site audit questionnaires to help you ask the right questions.

#### 4 Examine your random testing program.

Are there blocks of hours, days, weeks, or months when testing historically does not happen? Are there predictable gaps in testing that correlate to the

days and times when you are not on site? Does your transit system never test at the beginning of each quarter, month, or selection period? Does all testing end by December 20 of one year and resume after January 5 of the next year?

#### 5 Keep your vendors competitive.

While collection sites may be limited in your area, your Medical Review Officer, Third Party Administrator, and consortium may be located anywhere. There are many vendors willing to compete for your business, and finding one that offers the quality and level of service that you require may reduce the amount of time you spend correcting vendor errors.

#### 6 Communicate with the FTA.

Most transit systems know that MIS questions can be easily and quickly answered by calling the Volpe Center's D&A hotline (617-494-6336 or fta. damis@dot.gov), but many are not aware that general questions and even specific technical assistance is always available as well. The FTA welcomes requests for trainings, technical assistance, and program improvements, and is always an immediate and effective resource for providing you with answers and resources to make your testing program better.

The FTA offers hundreds of tools to make your program successful in addition to the trainings, seminars, and live technical assistance. By contacting the FTA, you are not raising red flags, instead, you are taking the responsible steps towards bettering your drug and alcohol testing program.

#### CHANTIX Use Poses Safety Risk for Transportation Professionals

Chantix (varenicline) is a prescription medicine used to help adults quit smoking. This drug, approved by the Food and Drug Administration (FDA) in 2006, has been widely advertised in the media. Since approval, approximately 21.8 million prescriptions have been dispensed. In 2007, the FDA reported that the agency was undertaking an ongoing safety review as patients taking Chantix experienced drowsiness that affected their ability to drive or operate machinery. In 2008, the FDA published a Public Health Advisory that reported some patients taking Chantix experienced vivid, unusual or strange dreams and again warned that patients taking Chantix may experience impairment of their ability to drive or operate machinery.

As a result of the research and FDA warning, the Federal Motor Carrier Safety Administration's (FMCSA) Administrator issued a statement on May 23, 2008 instructing medical examiners not to certify commercial drivers who were taking Chantix. Also in May 2008, the Federal Aviation Administration (FAA) banned Chantix use by pilots and air traffic controllers.

The DOT Office of Drug and Alcohol Policy and Compliance (ODAPC) issued a statement in June 2008 that reminded all transportation industries of the potential threat to public safety caused by the use of Chantix. The statement referenced an independent study that cited possible links to seizures, dizziness, heart irregularity, loss of consciousness, vision problems, diabetes, and more than 100 accidents. As a result, FTA in Issue 36 of this newsletter strongly urged all transportation industry employers to include in their employee training materials

appropriate information to address the dangers of Chantix.

Since 2008, the research and number of warnings has continued to grow. FDA received more serious side-effect reports for Chantix than for any other medication in the fourth quarter of 2007. FDA Drug Safety Communications listed the following risks associated with Chantix:

- Risk of changes in behavior, hostility, agitation, depressed mood, and suicidal thoughts or actions;
- Serious neuropsychiatric adverse events including suicidal ideation, suicide attempt, and completed suicide that occur soon after taking Chantix, several weeks after beginning treatment, or after stopping use of the medication;
- Possible new or worsening symptoms such as shortness of breath or trouble breathing, chest pain, and pain in legs while walking;

- Impairment of the ability to drive or operate heavy machinery; and
- Vivid, unusual, or strange dreams.
   In July 2011, the Pfizer Medication

Guide warned that users reported swelling of the face, mouth, and neck that can lead to life-threatening respiratory compromise. Other symptoms include abnormal thoughts, dangerous impulses, and hallucinations. Bad reactions have been linked to patients also taking insulin, asthma medicines, or blood thinners. Pfizer again advised patients to use caution when driving.

Given the potential threat to public safety caused by the use of Chantix by safety-sensitive employees, the FTA and ODAPC once again strongly encourage transit employers to educate employees regarding the risks associated with taking this medication and encourage employees to work with their prescribing medical practitioners to identify alternative treatments.

#### On-Duty Notification of Test Requirement

The purpose of the Federal Transit Administration's (FTA) drug and alcohol testing rules is to "help prevent accidents, injuries, and fatalities resulting from the misuse of alcohol and use of prohibited drugs by employees who perform safety-sensitive functions."

An employee covered under the FTA drug and alcohol testing regulations can only be randomly tested for alcohol misuse while the employee is performing safety-sensitive functions; just before the employee is to perform safety-sensitive functions; or just after the employee has ceased performing safety-sensitive functions. A covered employee may be randomly tested for prohibited drug use anytime while on duty (§655.45 (i)). Therefore, neither a drug test nor an alcohol test can be conducted on a covered employee when they are off duty.

Should an employer call an employee into work from an off-duty status consistent with the employer's (formal or informal) on-call policy and the employee chooses to report for duty, the employee will be subject to a drug test anytime during the shift and an alcohol test anytime during the shift when the employee performs safety-sensitive duties, just before or just after. If an employee does not (Continued on page 10)

#### Drug and Alcohol Training

FTA will be sponsoring upcoming training sessions to provide essential information to facilitate covered employers' compliance with the drug and alcohol testing regulations (49 CFR Part 655 and Part 40). These free one-day trainings are available on a first come, first serve basis. The schedule for these trainings will be coming out shortly and will be posted on the website below as they are scheduled.

For schedule information and to register for a training session go to http://transit-safety.fta.dot.gov/DrugAndAlcohol/Training.

If you are interested in hosting a one-day training session contact the FTA Drug and Alcohol Project Office at fta. damis@dot.gov or (617) 494-6336 for more information.

The Transportation Safety Institute (TSI) will once again offer the Substance

Abuse Management and Program Compliance and the Reasonable Suspicion Determination for Supervisors courses on a cost-recovery basis. To receive more information about their courses, please call (405) 954-3682 and to register go to http://www.tsi.dot.gov or http://transit-safety.safety.fta.dot.gov/DrugAndAlcohol/Training.

#### **Transit Safety Institute (TSI) Training Schedule**

•		
Title	Location	Date
Substance Abuse Management and Program Compliance	Tampa, FL	Feb. 13 – 15, 2012
Substance Abuse Management and Program Compliance	Everett, WA	March 05, 2012
Reasonable Suspicion Determination for Supervisors Seminar	San Antonio, TX	March 09, 2012
Substance Abuse Management and Program Compliance	Jackson, MS	June 4 – 6, 2012
Reasonable Suspicion Determination for Supervisors Seminar	Jackson, MS	June 07, 2012
Reasonable Suspicion Determination for Supervisors Seminar	Birmingham, AL	June 22, 2012

#### On-Duty Notification of Test Requirement

(Continued from page 9)
report for duty, this may be a violation of
the employer's attendance or on-call duty
policy, but it is not a violation of the FTA
regulation and should not be considered
a test refusal even if the primary purpose
for calling the employee in for duty was to
conduct a drug or alcohol test.

If the employer's intent is to conduct a random test on an employee during a specific work shift or assignment, but the employee takes leave and is off-duty before the employer informs the employee of the need for the test, this is not a test refusal. An employee can only be determined to have refused a test if the employee is informed of the test requirement while the employee is on duty.

#### Testing Following Self-Referral under Employer Authority

The primary goal of the Federal Transit Administration's (FTA) drug and alcohol testing regulations, 49 CFR Part 655, is to deter and detect prohibited drug use and alcohol misuse. As a consequence of the testing program and the associated training, safety-sensitive employees are made aware of the effects and consequences of prohibited drug use and alcohol misuse on personal health, safety, and the work environment. Employees also become aware of the consequences should they test positive or refuse a test under the employer's policy.

Many transit systems encourage employees to seek help if they believe they have a substance abuse or alcohol problem, but have yet to be detected by the testing program. Commonly, employers (under their own authority) add provisions within their drug and alcohol policy that encourage employees to make self-referrals to the employer's Employee Assistance Program (EAP) and to obtain the necessary treatment to address their drug and alcohol problems.

If the employer encourages self-referrals, the process must be clearly defined, with the elimination of as many barriers as possible. The employee should be made aware of the confidentiality protections, the nature of management reports, treatment requirements, testing requirements, leave policy, and the interrelationship with the FTA required testing program. **Employees should know that** (Continued on page 12)

#### Specimen Collection Quality Assurance Procedures

The urine specimen collection process, testing method, and quality assurance protocols for DOT drug tests are well-defined in 49 CFR Part 40. Each participant in the process (i.e., collector, laboratory, and Medical Review Officer (MRO)) has specific roles and responsibilities for quality assurance that are designed to ensure that problems are avoided and in the event that an error is made, it is corrected promptly in order to maintain the integrity of the testing process and the accuracy of the test.

The **collector** has the responsibility of trying to successfully complete a collection procedure for each employee. After completing a collection, but prior to placing Copy 1 of the Chain of Custody and Control Form (CCF) in a leakresistant plastic bag, the collector should review each of the sections on the CCF to ensure that all copies of the CCF are legible and complete. If before the donor leaves the collection facility, the collector becomes aware of a procedural or paperwork error that could compromise the test, the collector must try to correct the problem as soon as possible, if practicable. Most errors can be easily corrected on the CCF if the collector crosses out the wrong information, writes in the correct information, and initials the change. Other errors can be corrected by adding comments in the Remarks section in Step 2 of the CCF. If necessary, the collector may initiate another collection.

When the **HHS-certified laboratory** receives urine specimens with their corresponding CCF, laboratory personnel check to see if the specimen ID number



Knowing who does what in the collection process will help avoid problems. (© iStockPhoto/George Clerk)

on the specimen bottle seal matches the number on the CCF, check to see that the seal is intact, that there is sufficient specimen volume, and that the CCF has been properly completed by the collector including the collector's printed name. If an error or discrepancy is identified and it is correctable, the laboratory will contact the collector and request that a correction affidavit be created by the collector. In some cases, the lab will provide the correction affidavit to the collector. The laboratory has five business days to correct the flaw. If the error cannot be corrected by the collector (i.e., fatal flaw), the laboratory will report the test to the MRO as "Rejected for Testing."

As the impartial authority of the drug testing process, the **MRO** also conducts a quality assurance review of the CCF on all specimen collections to determine if there is a problem that may cause a test to be cancelled. If errors are identified, the MRO must provide feedback to

employers, collection sites, and laboratories regarding performance issues. The MRO must correct any errors uncovered during the MRO review process.

With all service agents doing their part to ensure the quality of the testing process, most problems are avoided or addressed without incident. The industry as a whole experiences very few fatal flaws. However, even with these checks and balances, problems get through undetected. The employer must remain diligent in its review of CCFs to ensure the accuracy of the test and integrity of the testing process (see FTA Drug and Alcohol Regulation Updates, Issue 43, Page 4). Each problem should be addressed individually, but if the employer identifies a pattern of problems that are being made at the collection site, and go undetected by the laboratory and MRO, these issues should be brought to the attention of the MRO and quality assurance procedures reviewed.



The FTA's drug and alcohol program addresses the administration's first strategic goal: "Promote the public health and safety by working toward the elimination of transit-related deaths, injuries, property damage, and the improvement of personal security and property protection." (© iStockPhoto/Pink Badger)

#### **Produced By:**

Federal Transit Administration Office of Safety and Security 1200 New Jersey Avenue, SE 4th Floor, East Building Washington, DC 20590

#### Written by:

U.S. Department of Transportation John A. Volpe National Transportation Systems Center 55 Broadway

Cambridge, MA 02142 MacroSys, LLC

55 Broadway Cambridge, MA 02142

Cahill Swift, LLC 240 Commercial Street Boston, MA 02109

RLS & Associates, Inc. 3131 South Dixie Highway/Suite 545 Dayton, OH 45439

#### Testing Following Self-Referral under Employer Authority

(Continued from page 9)

self-referral does not in any way shield them from FTA tests or the consequences of a positive result. If the individual is allowed to remain in his or her safety-sensitive position during self-referral treatment and/or the aftercare period, the employee is still subject to testing under all test categories including random.

All substance abuse testing that may be conducted as part of a self-referral evaluation, treatment, or aftercare program must be performed under company authority using non-DOT Chain of Custody and Control Forms (CCFs) and must not be reported on the employer's annual MIS report. An industry best practice is to remove the self-referring employee from safety-sensitive duties during treat-

#### "The primary goal is to deter and detect prohibited drug use and alcohol abuse."

ment, and mimic the DOT return-to-duty process by referring the employee to the employer's Substance Abuse Professional (SAP). Treatment and a follow-up assessment by the SAP would then be required before allowing the employee to return to safety-sensitive duties. Commonly, employees are required to enter into a return-to-work contract with the employer that requires the employee to participate in a follow-up testing program similar to the FTA follow-up testing requirements, comply with the SAP aftercare program, and adhere to other specified work standards.