

Ensuring Your Service Agent's Compliance

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FTA Drug and Alcohol Program National Conference
April 14-16, 2026



U.S. Department of Transportation
Federal Transit Administration

Disclaimer

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Speaker Introduction



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Agenda

1. Collection Site Compliance
2. Medical Review Officer (MRO) Compliance
3. Substance Abuse Professional (SAP) Compliance
4. Consortium/Third Party Administrator (C/TPA) Compliance



Reminder

- Your Service Agents May Not Always Be Right!
- You Need to Know and Understand the Regulations!



Running a Compliant Program



Many Components



A Compliant Program Takes Time

- General Company Responsibilities
 - OSHA
 - Worker's Comp
- FTA Drug and Alcohol Testing Program Responsibilities
 - New Hire Background Checks
 - Adding/Removing Employees to Random Testing
 - Violations and Discipline
- Etcetera, Etcetera, Etcetera



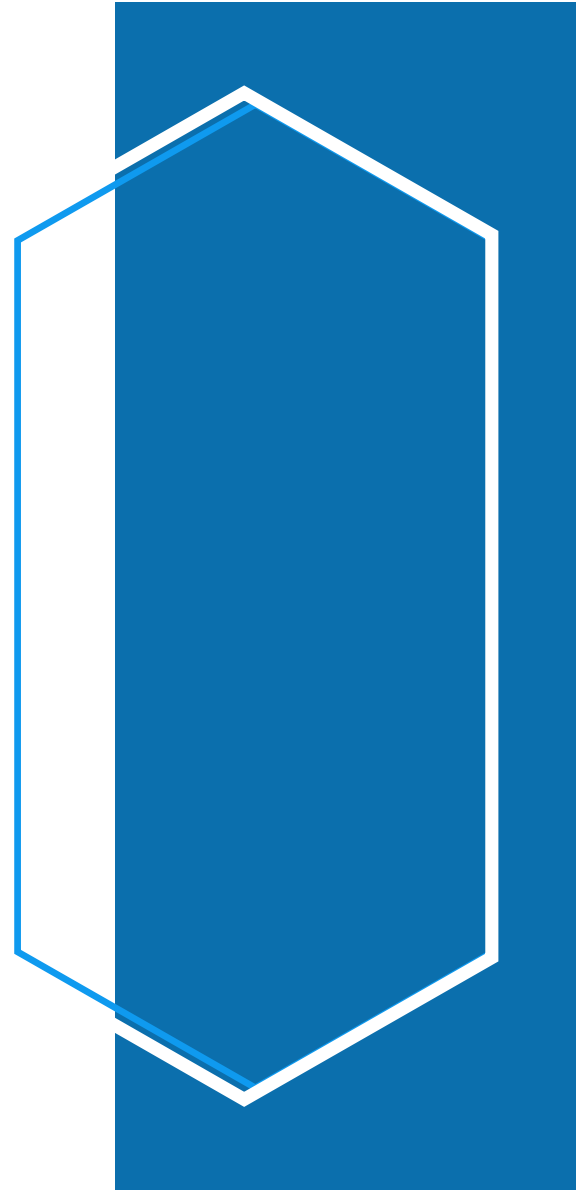
Service Agents Are There To ASSIST You!



Collection Site Compliance



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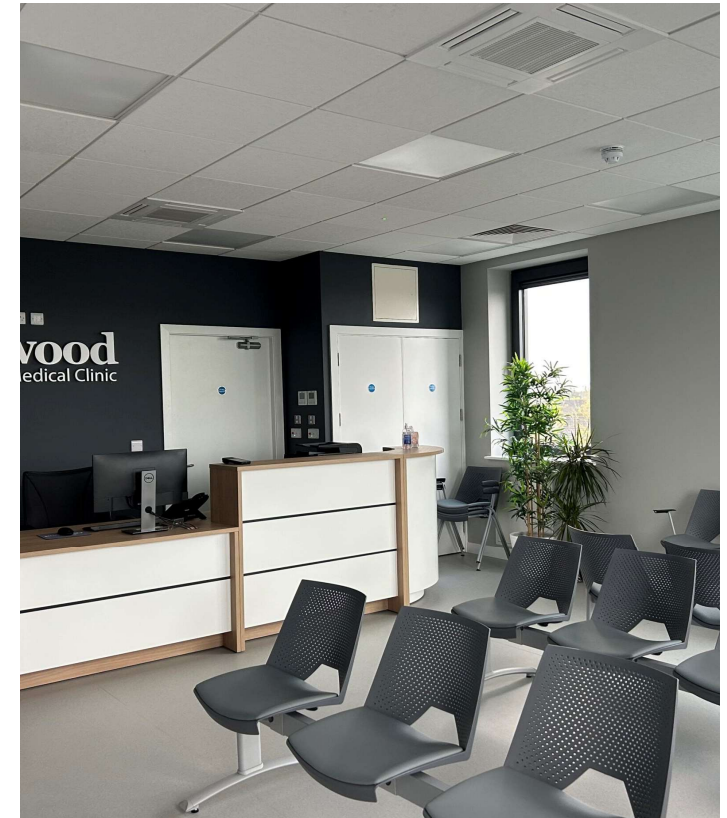
Regulations

Facility

Part 40, Subpart D

Must have all necessary **personnel, materials, equipment, facilities,** and supervision to provide for the **collection,** temporary storage, and shipping of urine specimens to a laboratory, and a suitable clean surface for writing.

49 CFR 40.42(c)



Personnel

Alcohol Testing

Trained - Qualified Technicians

- Screening Test Technician (STT)
 - Only Screening Tests
- Breath Alcohol Technician (BAT)
 - Screening Testing and Confirmation Testing

Drug Testing

Trained - Qualified Urine Collectors

Training

Alcohol Technicians

- Qualification Training
 - Particular device (ASD or EBT), Integrity
- Initial Proficiency
 - Mock collections (7 for BATs, 5 for STTs)
- Refresher Training
 - Every 5 years
- Error Correction Training
 - Within 30 days

49 CFR 40.213

Urine Collectors

- Qualification Training
 - Collection Steps, Problems, Fatal Flaws, Integrity
- Initial Proficiency
 - Mock collections (5)
- Refresher Training
 - Every 5 years
- Error Correction Training
 - Within 30 days

49 CFR 40.33

DOCUMENTATION – Must Be Maintained

All Service Agents – Collectors & Alcohol Technicians

Section 40.33(a) States:

You must be knowledgeable about this part, the current “DOT Urine Specimen Collection Procedures Guidelines,” and DOT agency regulations applicable to the employers for whom you perform collections. DOT agency regulations, the DOT Urine Specimen Collection Procedures Guidelines, and other materials are available from ODAPC (Department of Transportation, 1200 New Jersey Avenue SE., Washington DC, 20590, 202-366-3784, or on the ODAPC Web site (<https://www.transportation.gov/odapc>). You must keep current on any changes to these materials. You must subscribe to the ODAPC list-serve at: <https://www.transportation.gov/odapc/get-odapc-email-updates>.

Section 40.213(a) states:

You must be knowledgeable about the alcohol testing procedures in this part and the current DOT guidance. Procedures and guidance are available from ODAPC (Department of Transportation, 1200 New Jersey Avenue SE., Washington, DC 20590, 202-366-3784, or on the ODAPC Web site, <http://www.transportation.gov/odapc>). You must keep current on any changes to these materials. You must subscribe to the ODAPC list-serve at (<https://www.transportation.gov/odapc/get-odapc-email-updates>).

Materials

Breath Alcohol Collections

- Alcohol Testing Forms (ATF)
- Testing device
 - Supplies:
 - Sealed mouthpieces
 - Tamper evident tape (if results are not self-adhesive)

The image shows a sample of a U.S. Department of Transportation (DOT) Alcohol Testing Form. It is a multi-section document with fields for recording test results, including driver information, test details, and a section for the collector's signature and date. The form is titled "U.S. Department of Transportation (DOT) Alcohol Testing Form" and includes instructions for use.

Urine Collections

- Custody & Control Forms (CCF)
 - Sent with employee or housed at collection site
- Collection Kits
- Shipping containers or lab courier

The image shows a sample of a FEDERAL DRUG TESTING CUSTODY AND CONTROL FORM. It is a detailed document with multiple sections for recording test results, including specimen information, collector details, and a section for the collector's signature and date. The form is titled "FEDERAL DRUG TESTING CUSTODY AND CONTROL FORM" and includes instructions for use.

Equipment

Alcohol Collection Devices

Devices listed on ODAPC's web page

- Alcohol Screening Devices (ASDs)
- Evidential Breath Measurement Devices (EBTs)

40 CFR 40.229 - 40.231



Devices must be used per manufacturer's instructions.

- Must be inspected, maintained, and calibrated per manufacturer's instructions:
 - Per the Quality Assurance Plan (QAP)
 - Maintain records.

49 CFR 40.233 - 40.235

Security

Alcohol Testing

- Only authorized personnel
- Secure storage for devices
- Visual privacy
- Aural privacy

40 CFR 40.221 - 40.223

Drug Testing

- Secure water sources.
- Blue toilet water.
- Inspect for unauthorized substances.
- Secure moveable toilet tank tops or add bluing agent.
- Ensure no undetected access.
- Secure/remove areas of concealment.
- Re-check and secure collection area following each collection.

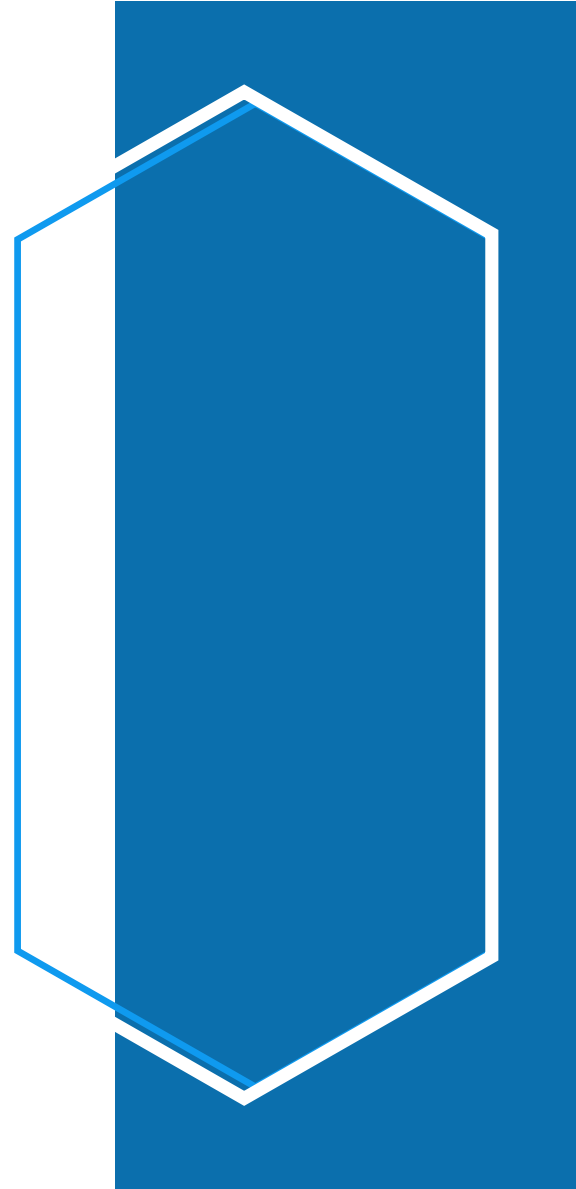
49 CFR 40.43

Problems with a Collection

Who Determines a Refusal?



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Employee leaves the collection site prior to completing a required 2nd drug test.

- Who determines the refusal?
 - Collector
 - Employer

49 CFR 40.191



The employee fails to sign Step 2 on the ATF.

- Who determines the refusal?
 - Collector
 - Employer

49 CFR 40.261

The employee admits to the collector that they adulterated their specimen.

- Who determines the refusal?
 - Collector
 - Employer

49 CFR 40.191

Employee fails to cooperate with the testing process by not emptying their pockets.

- Who determines the refusal?
 - Collector
 - Employer

49 CFR 40.191

Medical Review Officer Compliance



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Regulations – 49 CFR 40.121

- Credentials
 - Licensed physician
- Qualification Training
 - Collection procedures
 - CCF, reporting, and recordkeeping
 - Interpretation of drug and validity tests results
 - MRO roles and responsibilities in DOT drug testing
 - Interaction with other program participants (e.g., DERs, SAPs)
- Examination
 - Administered by a nationally-recognized MRO certification board or subspecialty board
- Requalification Training & Exam
 - Every 5 years



DOCUMENTATION – Must Be Maintained

All Service Agents - MRO

Section 40.121(b)(3) States:

You must be knowledgeable about this part, the DOT MRO Guidelines, and the DOT agency regulations applicable to the employers for whom you evaluate drug test results, and you must keep current on any changes to these materials. You must subscribe to the ODAPC list-serve at

<https://www.transportation.gov/odapc/get-odapc-email-updates>. DOT agency regulations, DOT MRO Guidelines, and other materials are available from ODAPC (Department of Transportation, 1200 New Jersey Avenue SE, Washington, DC 20590, 202-366-3784), or on the ODAPC Web site (<http://www.transportation.gov/odapc>).

Review Your Paperwork

- Ensure required observed tests were observed.
- Ensure a reason for cancellation is listed.
- Review negative-dilute protocols (40.197)
 - MRO required **immediate direct observation** retest (creatinine equal to or greater than 2mg/dL but less than or equal to 5 mg/dL)
 - If creatinine is greater than 5 mg/dL:
 - Employer policy – Do You Retest? If so, immediate, but no direct observation.

Problems with a Collection

Who Determines A Refusal?



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The MRO contacts the employer because they are unable to contact the employee. The employer informs the employee, but no contact is made to the MRO.

- Who determines the refusal?
 - MRO
 - Employer

An employee cannot produce a specimen. After being notified by the employer to go for a medical evaluation, they don't schedule an appointment.

- Who determines the refusal?
 - MRO
 - Employer

The employee admits to the MRO that they adulterated/substituted their specimen.

- Who determines the refusal?
 - MRO
 - Employer

Substance Abuse Professional (SAP)



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Regulations – 49 CFR 40.281

- Credentials
 - Licensed physician
 - Licensed or certified social worker, psychologist, employee assistance professional
 - State-licensed or certified marriage and family therapist
 - Drug and alcohol counselor certified by an organization listed at <https://www.transportation.gov/odapc/sap>
- Basic Knowledge:
 - Knowledgeable and have clinical experience in diagnosis and treatment of alcohol and controlled substances-related disorders.
 - Knowledgeable about SAP function as it relates to employer interests in safety-sensitive duties.



Regulations, continued

- Qualification Training
 - Instruction on:
 - Background, rationale, and coverage of the Department's drug & alcohol testing program
 - Part 40 and DOT agency testing rules
 - Drug and alcohol testing requirements: collections, laboratory testing, MRO review, problems in drug and alcohol testing, role of BATs and STTs
 - SAP qualifications and prohibitions
 - SAP role in the return-to duty process
 - SAP consultation with employers, MROs, and treatment providers
 - Reporting and record keeping
 - Issues SAPs confront in carrying out their duties

Regulations, continued

- Examination
- Continuing Education
 - 12 professional development hours every 3 years
- Limitations
 - Remote evaluations must abide by geographic limitations applicable to the SAP's credential

DOCUMENTATION – Must Be Maintained

All Service Agents - SAP

Section 40.281(b)(3) states:

You must be knowledgeable about this part, the DOT agency regulations applicable to the employers for whom you evaluate employees, and the DOT SAP Guidelines.

You must keep current on any changes to these materials. You must subscribe to the ODAPC list-serve at <https://www.transportation.gov/odapc/get-odapc-email-updates>. DOT agency regulations, DOT SAP Guidelines, and other materials are available from ODAPC (Department of Transportation, 1200 New Jersey Avenue SE., Washington DC, 20590 (202-366-3784), or on the ODAPC Web site (<http://www.transportation.gov/odapc>).

Whose Choice is it Anyway?

Who Makes the Decision



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Who Chooses?

An employee has complied with the SAP education and/or treatment program. The SAP sends the documentation to the employer that the employee is able to return to safety-sensitive functions. The employer hired someone to run the routes while the employee with the violation was going through the return-to-duty process. Upon receiving the letter from the SAP, the employer conducts the return-to-duty test as stated and puts the employee and new hire on part time shifts.

Was the agency required to return the employee to safety-sensitive duties since they completed the SAP requirements?

No – an employer is not required to return an employee to safety-sensitive duties, subject to collective bargaining agreements or other legal requirements.

49 CFR 40.305(b)

Consortium/Third Party Administrator Compliance



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Regulations

Sections 40.345(a) and (c) states:

(a) As a C/TPA or other service agent, you may act as an intermediary in the transmission of drug and alcohol testing information in the circumstances specified in this section only if the employer chooses to have you do so. Each employer makes the decision about whether to receive some or all of this information from you, acting as an intermediary, rather than directly from the service agent who originates the information (e.g., an MRO or BAT).

(c) In every case, you must ensure that, in transmitting information to employers, you meet all requirements (e.g., concerning confidentiality and timing) that would apply if the service agent originating the information (e.g., an MRO or collector) sent the information directly to the employer. For example, if you transmit drug testing results from MROs to DERs, you must transmit each drug test result to the DER in compliance with the MRO requirements set forth in [§ 40.167](#).

Regulations, continued

49 CFR 40.347- 40.351; 40.355(k)

Qualifications: NONE

Examinations: NONE

May:

- Operate random testing programs
- Assist employers in ensuring follow-up testing
- Receive and maintain records
 - Simultaneous receipt from MRO or BAT or, if an intermediary, transmitted in same time periods as required elsewhere in Part 40
- Transfer all records immediately on request from an employer
- Same confidentiality and record retention as an employer

May Not:

- Be designated as the Designated Employer Representative (DER)

Regulations, continued

Appendix H to Part 40 states:

1. If you are a C/TPA, you may, acting as an intermediary, transmit the information in the following sections of this part to the DER for an employer, if the employer chooses to have you do so. These are the only items that you are permitted to transmit to the employer as an intermediary. The use of C/TPA intermediaries is prohibited in all other cases, such as transmission of laboratory drug test results to MROs, the transmission of medical information from MROs to employers, the transmission of SAP reports to employers, the transmission of positive alcohol test results, and the transmission of medical information from MROs to employers.
2. In every case, you must ensure that, in transmitting the information, you meet all requirements (e.g., concerning confidentiality and timing) that would apply if the party originating the information (e.g., an MRO or collector) sent the information directly to the employer. For example, if you transmit MROs' drug testing results to DERs, you must transmit each drug test result to the DER in compliance with the requirements for MROs set forth in [§ 40.167](#).

Choose Wisely

Remember: The employer is ultimately responsible for compliance with DOT/FTA regulations, even when using a service agent.

- Do they provide the services you need?
 - **Remember:** It is important they understand the differences between FMCSA and FTA (or other agencies).
- Do they provide the services the way you need them?
 - **Remember:** You choose what works best for you.

What Can They Do For You?



You Choose!

Drug and Alcohol Policy

Templates

- Read over for compliance and know what is in there
 - Alter to fit your employer
- Ensure FTA requirements (§ 655.15) are met
 - Policy Requirements Checklist:

<https://transit-safety.fta.dot.gov/DrugAndAlcohol/Tools/>

FTA also offers a free policy builder: <https://transit-safety.fta.dot.gov/drugandalcohol/tools/PolicyBuilder/CreatePolicy.aspx>

Determinations

Who makes them



Who Makes the Determination?

An employer with a second chance policy has received the initial evaluation and the letter of compliance for an employee from the SAP. A negative return-to-duty drug test result is received, and the employee is returned to safety-sensitive functions.

The employer has started using a TPA and provides them a copy of the follow-up testing plan to help them stay on track with the tests. The first notification of follow-up testing arrives and states that the employee should be drug tested on March 15th. The employee is not scheduled to work on March 15th.

Should the employer call the employee in for the follow-up test?

NO – Follow-up drug tests should be performed while the employee is on duty. The TPA does not determine the date of the test.

The Employer, not the C/TPA must...

- Make post-accident testing determinations.
- Make reasonable suspicion testing determinations.
- Be the Designated Employer Representative (DER).
- Determine dates for random, return-to-duty, or follow-up testing.

49 CFR 40.355



Scenarios

Do you know how they should be handled?



Scenario #1

A transit agency uses a TPA to help run their FTA drug and alcohol program. The TPA provides collection sites, a laboratory, and MRO services. The TPA does not maintain records on behalf of the employer. All the testing information is uploaded to a portal where the employer may view or print their testing information. This includes lab statistical summaries, MRO-verified drug test results, and alcohol test results reports.

The employer never receives any ATFs so they are unsure of and unable to document results. An FTA audit resulted in a finding to the employer for lack of appropriate documentation.

The collection site is also non-compliant for only using the electronic alcohol documentation.

Correct Answer

The employer is **required** to keep records of alcohol results (e.g. the ATF.)

40.225(a) The DOT Alcohol Testing Form (ATF) must be used for every DOT alcohol test. The ATF must be a three-part carbonless manifold form. The ATF is found in appendix I to this part. You may view this form on the ODAPC web site (<http://www.transportation.gov/odapc>).

40.333(a): As an employer, you must keep the following records for the following periods of time:

- 5 years: Records of alcohol test results indicating an alcohol concentration of 0.02 or greater
- 1 year: Records of negative and cancelled alcohol test results with a concentration of less than 0.02

The Wrong and The Right

Alcohol
Test
"Result"

Alcohol Test Information

DONOR INFORMATION
 Donor ID: [REDACTED]
 Donor Name: [REDACTED]
 Employer: [REDACTED] - FTA

TEST INFORMATION
 Test Reason: Random
 Test Type: DOT
 Test Facility: [REDACTED]
 Technician: [REDACTED]

RESULT INFORMATION - SCREENING
 Test Date: 07/30/2020 2:03 PM
 Test #: 0830
 Result: 0.000
 Device Type: Breath
 Device Name: Intoxilyser 240
 Test Entered on 08/04/2020 12:05 PM

* This report does not meet DOT record requirements. Employers must maintain the employer copy of the DOT Alcohol Test Form.

Alcohol
Testing
Form

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INSERT

**U.S. Department of Transportation (DOT)
Alcohol Testing Form**
(The instructions for completing this form are on the back of Copy 3.)

STEP 1: TO BE COMPLETED BY ALCOHOL TECHNICIAN

A: Employee Name _____
(Print) (First, M.I., Last)

B: SNN or Employee ID No. _____

C: Employer Name _____
Street _____
City, State, Zip _____

DER Name and Telephone No. _____
DER Name _____ DER (Area Code & Phone Number) _____

D: Reason for Test: Random Reasonable Susp. Post-Accident Return to Duty Follow-up Pre-employment

STEP 2: TO BE COMPLETED BY EMPLOYEE

I certify that I am about to submit to alcohol testing required by U.S. Department of Transportation regulations and that the identifying information provided on the form is true and correct.

Signature of Employee _____ Date: Month / Day / Year _____

STEP 3: TO BE COMPLETED BY ALCOHOL TECHNICIAN

(If the technician conducting the screening test is not the same technician who will be conducting the confirmation test, each technician must complete their own form.) I certify that I have conducted alcohol testing on the above named individual in accordance with the procedures established in the U.S. Department of Transportation regulation, 49 CFR Part 40, that I am qualified to operate the testing device(s) identified, and that the results are as recorded.

TECHNICIAN: BAT STT DEVICE: SALIVA BREATH* IS-Minute Wait: Yes No

SCREENING TEST: (For BREATH DEVICE* write in the space below only if the testing device is not designed to print.)

Test #	Testing Device Name	Device Serial # OR Lot # & Exp. Date	Activation Time	Reading Time	Result

CONFIRMATION TEST: Results **MUST** be affixed to each copy of this form or printed directly onto the form.

REMARKS: _____

Alcohol Technician's Company _____ Company Street Address _____
 (PRINT) Alcohol Technician's Name (First, M.I., Last) _____ Company City, State, Zip _____
 Phone Number (Area Code & Number) _____

Signature of Alcohol Technician _____ Date: Month / Day / Year _____

STEP 4: TO BE COMPLETED BY EMPLOYEE IF TEST RESULT IS 0.02 OR HIGHER

I certify that I have submitted to the alcohol test, the results of which are accurately recorded on this form. I understand that I must not drive, perform safety-sensitive duties, or operate heavy equipment because the results are 0.02 or greater.

Signature of Employee _____ Date: Month / Day / Year _____

Form DOT F 1360 (Rev. 6/2008) OMB No. 2105-0029
 COPY 1 - ORIGINAL - FORWARD TO THE EMPLOYER 470-FS-C3 (Rev. 1/11) 6362

Print Screening Results Here or Affix with Tamper Evident Tape

Print Confirmation Results Here or Affix with Tamper Evident Tape

Print Additional Results Here or Affix with Tamper Evident Tape

Scenario #2

An employee goes in for a random drug test. The first specimen is cold, and the collector informs the employee they need to bag up the first specimen, and they will need to collect a second specimen under direct observation.

After immediately taking the employee in for a second collection, the employee is unable to provide, and the collector begins the shy bladder process. During the waiting period the employee decides to leave.

What does the collector do with the initial cold specimen?

Scenario #2, cont'd

The collector ships the cold specimen to the lab.

More than likely this specimen is reported to the MRO as negative, specimen 1 of 2.

If the MRO incorrectly reports this result to the employer without waiting for a second specimen result, the employer could act on the result and inappropriately maintain the employee in their safety-sensitive function.

Correct Answer

The collector must notify the DER. As soon as the collector notifies the DER, the collector must discard the initial specimen, as the donor has refused to complete the testing process.

The collector must complete the second CCF, noting in the remarks that the donor left the collection site prior to completing the collection under direct observation after providing a specimen with a temperature out of range.

CCFs are sent to the DER and the MRO.

The refusal is determined by the EMPLOYER not the MRO.

49 CFR 40.65(b)(7)

Scenario #3

It is determined through a medical evaluation that an employee does not have a valid reason for being unable to produce an adequate specimen. The test is deemed a refusal by the MRO, and the employer, who has a second chance policy; provides the donor with the SAP referral.

The employee goes to the SAP and explains that although it was determined they don't have a medical reason to not produce, they have a problem using the bathroom every time they are tested. The SAP meets with this employee twice, and determines no education/treatment are needed, and provides the employer a compliance letter stating the employee may return to duty, along with the follow-up plan,

Scenario #3, cont'd

- The employee could be using a prohibited substance hoping to pass any testing scenarios (i.e., randoms, follow-ups).
- The employee is returned to safety-sensitive functions and could have a fatal accident.
- The employer and SAP when audited by FTA will end up with findings for non-compliance.

Correct Answer

The SAP is required to recommend a course of education and/or treatment.

49 CFR 40.293(b)

- If an employer realizes that none were recommended, and the employee only met with the SAP), the employer may push back.
- If the SAP is not providing services as required by the regulations, the employer may obtain the services of another provider. Provide the information to ODAPC and document your reasoning.
- May require the employee to see another SAP to return to safety-sensitive functions.

Scenario #4

An employer uses a C/TPA for their random selections. The employer is encouraged by the C/TPA to update their random list regularly (i.e., remove employees when terminated, add new hires once they receive an MRO-verified negative result).

The C/TPA provides the list of selected employees one week prior to the beginning of each selection period to ensure that testing may be scheduled.

To ensure accuracy and timeliness, the C/TPA also requires that testing is completed before the last 2 weeks of the selection period so that they may determine selection percentages for the next testing period.

Scenario #4, cont'd

- Random testing becomes predictable.
- When audited by FTA, the transit agency receives a finding for not spreading their random testing.
- TPA receives a finding for limiting the agency's selection period.

Correct Answer

- The employer needs to spread testing reasonably throughout the calendar year. Therefore, they need to inform the TPA that they cannot limit the time within the selection period.
- 49 CFR 655.45(g)
- Random testing must be unpredictable. Whether the selection period is a month or a quarter, the transit agency cannot have a predictable pattern of not testing 2 weeks prior to its end.

Oversight

Best Practices for Compliance



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Ask Questions

All service agents:

- How long have they been in business?
- What services do they provide?
- Are they familiar with DOT and FTA regulations? How many other FTA clients do they have?
- Do they assist with providing required documentation?

Ask Questions

Collection site:

- How many testing locations in your area?
- Is there a location(s) available for off-hours testing?
- Do they perform on-site collections?
- Are Collector/BAT qualifications up-to-date?
- References – Do they have other employers you may speak to?



Ask Questions

MRO:

- Are qualifications up-to-date?
- What are the procedures for notifications of test results?
 - Phone call for positive verifications?
- References – Do they have other employers you may speak to?



Ask Questions

C/TPA:

- Do they provide/assist with documentation?
 - Management Information System (MIS)
 - Random Compliance – single pool/consortium
 - Semi-annual laboratory statistical summaries
 - Sent to TPA or you directly
 - Ensure for your employer only
- References – Do they have other employers you may speak to?
- Do they have other FTA clients? How many?

Review Paperwork

- Ensure the correct agency.
- SSN/Emp ID used
 - CDL # could erroneously land your employee in the FMCSA Clearinghouse.
- All sections filled out correctly (missing signatures, etc.)
- Remarks if necessary
- CCF - Directly observed (checked if it was required)
- CCF - No “shadowing”
- ATF - No written results if the EBT prints
- ATF - Yes/No for “15-Minute Wait” only checked if a confirmation test was required

Reminder

- You pay service agents to provide services to **assist** you in running your program!
- The **employer** is ultimately responsible for compliance with FTA/DOT regulations, even when using a service agent.
- You Need to Know the Regulations and Requirements and make sure what your service agents provide are **compliant and works for you.**

Thank you!

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