

49 CFR PART 40 - PROCEDURES FOR TRANSPORTATION WORKPLACE DRUG & ALCOHOL TESTING PROGRAMS

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Subpart A - Administrative Provisions

§ 40.1

Who does this regulation cover?

- (a) This part tells all parties who conduct drug and alcohol tests required by Department of Transportation (DOT) agency regulations how to conduct these tests and what procedures to use.
- (b) This part concerns the activities of transportation employers, safety-sensitive transportation employees (including self-employed individuals, contractors and volunteers as covered by DOT agency regulations), and service agents.
- (c) Nothing in this part is intended to supersede or conflict with the implementation of the Federal Railroad Administration's post-accident testing program (see 49 CFR 219.200).

§ 40.3

What do the terms used in this part mean?

In this part, the terms listed in this section have the following meanings:

Adulterated specimen. 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.

Affiliate. Persons are affiliates of one another if, directly or indirectly, one controls or has the power to control the other, or a third party controls or has the power to control both. Indicators of control include, but are not limited to: interlocking management or ownership; shared interest among family members; shared facilities or equipment; or common use of employees. Following the issuance of a public interest exclusion, an organization having the same or similar management, ownership, or principal employees as the service agent concerning whom a public interest exclusion is in effect is regarded as an affiliate. This definition is used in connection with the public interest exclusion procedures of Subpart R of this part.

Air blank. In evidential breath testing devices (EBTs) using gas chromatography technology, a reading of the device's internal standard. In all other EBTs, a reading of ambient air containing no alcohol.

Alcohol. The intoxicating agent in beverage alcohol, ethyl alcohol or other low molecular weight alcohols, including methyl or isopropyl alcohol.

Alcohol concentration. The alcohol in a volume of breath expressed in terms of grams of alcohol per 210 liters of breath as indicated by a breath test under this part.

Alcohol confirmation test. A subsequent test using an EBT, following a screening test with a result of 0.02 or greater, that provides quantitative data about the alcohol concentration.

Alcohol screening device (ASD). A breath or saliva device, other than an EBT, that is approved by the National Highway Traffic Safety Administration (NHTSA) and placed

on a conforming products list (CPL) for such devices.

Alcohol screening test. An analytic procedure to determine whether an employee may have a prohibited concentration of alcohol in a breath or saliva specimen.

Alcohol testing site. A place selected by the employer where employees present themselves for the purpose of providing breath or saliva for an alcohol test.

Alcohol use. The drinking or swallowing of any beverage, liquid mixture or preparation (including any medication), containing alcohol.

Aliquot. A fractional part of a specimen used for testing. It is taken as a sample representing the whole specimen.

Blind specimen or blind performance test specimen. A specimen submitted to a laboratory for quality control testing purposes, with a fictitious identifier, so that the laboratory cannot distinguish it from an employee specimen.

Breath Alcohol Technician (BAT). A person who instructs and assists employees in the alcohol testing process and operates an evidential breath testing device.

Cancelled test. A drug or alcohol test that has a problem identified that cannot be or has not been corrected, or which this part otherwise requires to be cancelled. A cancelled test is neither a positive nor a negative test.

Chain of custody. The procedure used to document the handling of the urine specimen from the time the employee gives the specimen to the collector until the specimen is destroyed. This procedure uses the Federal Drug Testing Custody and Control Form (CCF) as approved by the Office of Management and Budget.

Collection container. A container into which the employee urinates to provide the specimen for a drug test.

Collection site. A place selected by the employer where employees present themselves for the purpose of providing a urine specimen for a drug test.

Collector. A person who instructs and assists employees at a collection site, who receives and makes an initial inspection of the specimen provided by those employees, and who initiates and completes the CCF.

Confirmatory drug test. 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.

Confirmatory validity test. A second test performed on different aliquot of the original urine specimen to further support a validity test result.

Confirmed drug test. A confirmation test result received by an MRO from a laboratory.

Consortium/Third-party administrator (C/TPA). A service agent that provides or coordinates the provision of a variety of drug and alcohol testing services to employers. C/TPAs typically perform administrative tasks concerning the operation of the employers' drug and alcohol testing programs. This term includes, but is not limited to, groups of employers who join together to administer, as a single entity, the DOT drug and alcohol testing programs of

its members. C/TPAs are not "employers" for purposes of this part.

Continuing education. Training substance abuse professionals (SAPs) who have completed qualification training and are performing SAP functions, designed to keep SAPs current on changes and developments in the DOT drug and alcohol testing program.

Designated employer representative (DER). An employee authorized by the employer to take immediate action(s) to remove employees from safety-sensitive duties, or cause employees to be removed from these covered duties, and to make required decisions in the testing and evaluation processes. The DER also receives test results and other communications for the employer, consistent with the requirements of this part. Service agents cannot act as DERs.

Dilute specimen. A urine specimen with creatinine and specific gravity values that are lower than expected for human urine.

DOT, The Department, DOT agency. These terms encompass all DOT agencies, including, but not limited to, the United States Coast Guard (USCG), the Federal Aviation Administration (FAA), the Federal Railroad Administration (FRA), the Federal Motor Carrier Safety Administration (FMCSA), the Federal Transit Administration (FTA), the National Highway Traffic Safety Administration (NHTSA), the Pipeline and Hazardous Materials Safety Administration (PHMSA), and the Office of the Secretary (OST). These terms include any designee of a DOT agency.

Drugs. The drugs for which tests are required under this part and DOT agency regulations are marijuana, cocaine, amphetamines, phencyclidine (PCP), and opiates.

Employee. Any person who is designated in a DOT agency regulation as subject to drug testing and/or alcohol testing. The term includes individuals currently performing safety-sensitive functions designated in DOT agency regulations and applicants for employment subject to pre-employment testing. For purposes of drug testing under this part, the term employee has the same meaning as the term "donor" as found on CCF and related guidance materials produced by the Department of Health and Human Services.

Employer. A person or entity employing one or more employees (including an individual who is self-employed) subject to DOT agency regulations requiring compliance with this part. The term includes an employer's officers, representatives, and management personnel. Service agents are not employers for the purposes of this part.

Error Correction Training. Training provided to BATs, collectors, and screening test technicians (STTs) following an error that resulted in the cancellation of a drug or alcohol test. Error correction training must be provided in person or by a means that provides real-time observation and interaction between the instructor and trainee.

Evidential Breath Testing Device (EBT). A device approved by NHTSA for the

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evidential testing of breath at the .02 and .04 alcohol concentrations, placed on NHTSA's Conforming Products List (CPL) for "Evidential Breath Measurement Devices" and identified on the CPL as conforming with the model specifications available from NHTSA's Traffic Safety Program.

HHS. The Department of Health and Human Services or any designee of the Secretary, Department of Health and Human Services.

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

Initial specimen validity test. The first test used to determine if a urine specimen is adulterated, diluted, substituted or invalid.

Invalid drug test. The result reported by a laboratory for a urine specimen that contains an unidentified adulterant, contains an unidentified interfering substance, has an abnormal physical characteristic, or has an endogenous substance at an abnormal concentration that prevents the laboratory from completing testing or obtaining a valid drug test result.

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

Medical Review Officer (MRO). A person who is a licensed physician and who is responsible for receiving and reviewing laboratory results generated by an employer's drug testing program and evaluating medical explanations for certain drug test results.

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.

Non-negative specimen. A urine specimen that is reported as adulterated, substituted, positive (for drug(s) or drug metabolite(s)), and/or invalid

Office of Drug and Alcohol Policy and Compliance (ODAPC). The office in the Office of the Secretary, DOT, that is responsible for coordinating drug and alcohol testing program matters within the Department and providing information concerning the implementation of this part.

Oxidizing adulterant. A substance that acts alone or in combination with other substances to oxidize drugs or drug metabolites to prevent the detection of the drug or drug

metabolites, or affects the reagents in either the initial or confirmatory drug test.

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

Primary specimen. In drug testing, the urine specimen bottle that is opened and tested by a first laboratory to determine whether the employee has a drug or drug metabolite in his or her system; and for the purpose of validity testing. The primary specimen is distinguished from the split specimen, defined in this section.

Qualification Training. The training required in order for a collector, BAT, MRO, SAP, or STT to be qualified to perform their functions in the DOT drug and alcohol testing program. Qualification training may be provided by any appropriate means (e.g., classroom instruction, internet application, CD-ROM, video).

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

Refresher Training. The training required periodically for qualified collectors, BATs, and STTs to review basic requirements and provide instruction concerning changes in technology (e.g., new testing methods that may be authorized) and amendments, interpretations, guidance, and issues concerning this part and DOT agency drug and alcohol testing regulations. Refresher training can be provided by any appropriate means (e.g., classroom instruction, internet application, CD-ROM, video).

Rejected for testing. 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

Screening Drug Test. See Initial drug test definition above.

Screening Test Technician (STT). A person who instructs and assists employees in the alcohol testing process and operates an ASD.

Secretary. The Secretary of Transportation or the Secretary's designee.

Service agent. Any person or entity, other than an employee of the employer, who provides services specified under this part to employers and/or employees in connection with DOT drug and alcohol testing requirements. This includes, but is not limited to, collectors, BATs and STTs, laboratories, MROs, substance abuse professionals, and C/TPAs. To act as service agents, persons and organizations must meet the qualifications set forth in applicable sections of this part. Service agents are not employers for purposes of this part.

Shipping container. A container that is used for transporting and protecting urine specimen bottles and associated documents from the collection site to the laboratory.

Specimen bottle. The bottle that, after being sealed and labeled according to the procedures in this part, is used to hold the urine specimen during transportation to the laboratory.

Split specimen. In drug testing, a part of the urine specimen that is sent to a first laboratory and retained unopened, and which is transported to a second laboratory in the event that the employee requests that it be tested following a verified positive test of the primary specimen or a verified adulterated or substituted test result.

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).

Stand-down. The practice of temporarily removing an employee from the performance of safety-sensitive functions based only on a report from a laboratory to the MRO of a confirmed positive test for a drug or drug metabolite, an adulterated test, or a substituted test, before the MRO has completed verification of the test result.

Substance Abuse Professional (SAP). A person who evaluates employees who have violated a DOT drug and alcohol regulation and makes recommendations concerning education, treatment, follow-up testing, and aftercare.

Substituted specimen. A urine specimen with creatinine and specific gravity values that are so diminished or so divergent that they are not consistent with normal human urine.

Verified test. A drug test result or validity testing result from an HHS-certified laboratory that has undergone review and final determination by the MRO.

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§ 40.5

Who issues authoritative interpretations of this regulation?

ODAPC and the DOT Office of General Counsel (OGC) provide written interpretations of the provisions of this part. These written DOT interpretations are the only official and authoritative interpretations concerning the provisions of this part. DOT agencies may incorporate ODAPC/OGC interpretations in written guidance they issue concerning drug and alcohol testing matters. Only Part 40 interpretations issued after August 1, 2001, are considered valid.

§ 40.7

How can you get an exemption from a requirement in this regulation?

- If you want an exemption from any provision of this part, you must request it in writing from the Office of the Secretary of Transportation, under the provisions and standards of 49 CFR part 5. You must send requests for an exemption to the following address: Department of Transportation, Deputy Assistant General Counsel for Regulation and Enforcement, 400 7th Street, SW., Room 10424, Washington, DC 20590.
- Under the standards of 49 CFR part 5, we will grant the request only if the request documents special or exceptional

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circumstances, not likely to be generally applicable and not contemplated in connection with the rulemaking that established this part, that make your compliance with a specific provision of this part impracticable.

- (c) If we grant you an exemption, you must agree to take steps we specify to comply with the intent of the provision from which an exemption is granted.
- (d) We will issue written responses to all exemption requests.

Subpart B - Employer Responsibilities

§ 40.11

What are the general responsibilities of employers under this regulation?

- (a) As an employer, you are responsible for meeting all applicable requirements and procedures of this part.
- (b) You are responsible for all actions of your officials, representatives, and agents (including service agents) in carrying out the requirements of the DOT agency regulations.
- (c) All agreements and arrangements, written or unwritten, between and among employers and service agents concerning the implementation of DOT drug and alcohol testing requirements are deemed, as a matter of law, to require compliance with all applicable provisions of this part and DOT agency drug and alcohol testing regulations. Compliance with these provisions is a material term of all such agreements and arrangements.

§ 40.13

How do DOT drug and alcohol tests relate to non-DOT tests?

- (a) DOT tests must be completely separate from non-DOT tests in all respects.
- (b) DOT tests must take priority and must be conducted and completed before a non-DOT test is begun. For example, you must discard any excess urine left over from a DOT test and collect a separate void for the subsequent non-DOT test.
- (c) Except as provided in paragraph (d) of this section, you must not perform any tests on DOT urine or breath specimens other than those specifically authorized by this part or DOT agency regulations. For example, you may not test a DOT urine specimen for additional drugs, and a laboratory is prohibited from making a DOT urine specimen available for a DNA test or other types of specimen identity testing.
- (d) The single exception to paragraph (c) of this section is when a DOT drug test collection is conducted as part of a physical examination required by DOT agency regulations. It is permissible to conduct required medical tests related to this physical examination (e.g., for glucose) on any urine remaining in the collection container after the drug test urine specimens have been sealed into the specimen bottles.
- (e) No one is permitted to change or disregard the results of DOT tests based on the results of non-DOT tests. For example, as an

employer you must not disregard a verified positive DOT drug test result because the employee presents a negative test result from a blood or urine specimen collected by the employee's physician or a DNA test result purporting to question the identity of the DOT specimen.

- (f) As an employer, you must not use the CCF or the ATF in your non-DOT drug and alcohol testing programs. This prohibition includes the use of the DOT forms with references to DOT programs and agencies crossed out. You also must always use the CCF and ATF for all your DOT-mandated drug and alcohol tests.

§ 40.14

What collection information must employers provide to collectors?

As an employer, or an employer's service agent—for example a C/TPA, you must ensure the collector has the following information when conducting a urine specimen collection for you:

- (a) Full name of the employee being tested.
- (b) Employee SSN or ID number.
- (c) Laboratory name and address (can be pre-printed on the CCF).
- (d) Employer name, address, phone number, and fax number (can be pre-printed on the CCF at Step 1-A).
- (e) DER information required at §40.35 of this part.
- (f) MRO name, address, phone number, and fax number (can be pre-printed on the CCF at Step 1-B).
- (g) The DOT Agency which regulates the employee's safety-sensitive duties (the checkmark can be pre-printed in the appropriate box on the CCF at Step 1-D).
- (h) Test reason, as appropriate: Pre-employment; Random; Reasonable Suspicion/Reasonable Cause; Post-Accident; Return-to-Duty; and Follow-up.
- (i) Whether the test is to be observed or not (see §40.67 of this part).
- (j) (Optional) C/TPA name, address, phone, and fax number (can be pre-printed on the CCF).

[65 FR 79526, Dec. 19, 2000, Sept. 27, 2010]

§ 40.15

May an employer use a service agent to meet DOT drug and alcohol testing requirements?

- (a) As an employer, you may use a service agent to perform the tasks needed to comply with this part and DOT agency drug and alcohol testing regulations, consistent with the requirements of Subpart Q and other applicable provisions of this part.
- (b) As an employer, you are responsible for ensuring that the service agents you use meet the qualifications set forth in this part (e.g., §40.121 for MROs). You may require service agents to show you documentation that they meet the requirements of this part (e.g., documentation of MRO qualifications required by §40.121(e)).
- (c) You remain responsible for compliance with all applicable requirements of this part and other DOT drug and alcohol testing regulations, even when you use a service agent. If you violate this part or other DOT drug and alcohol testing regulations because a service agent has not provided

services as our rules require, a DOT agency can subject you to sanctions. Your good faith use of a service agent is not a defense in an enforcement action initiated by a DOT agency in which your alleged noncompliance with this part or a DOT agency drug and alcohol regulation may have resulted from the service agent's conduct.

- (d) As an employer, you must not permit a service agent to act as your DER.

[65 FR 79526, Dec.19, 2000, as amended at 75 FR 59107, September 27, 2010]

§ 40.17

Is an employer responsible for obtaining information from its service agents?

Yes, as an employer, you are responsible for obtaining information required by this part from your service agents. This is true whether or not you choose to use a C/TPA as an intermediary in transmitting information to you. For example, suppose an applicant for a safety-sensitive job takes a pre-employment drug test, but there is a significant delay in your receipt of the test result from an MRO or C/TPA. You must not assume that "no news is good news" and permit the applicant to perform safety-sensitive duties before receiving the result. This is a violation of the Department's regulations.

§ 40.21

May an employer stand down an employee before the MRO has completed the verification process?

- (a) As an employer, you are prohibited from standing employees down, except consistent with a waiver a DOT agency grants under this section.
- (b) You may make a request to the concerned DOT agency for a waiver from the prohibition of paragraph (a) of this section. Such a waiver, if granted, permits you to stand an employee down following the MRO's receipt of a laboratory report of a confirmed positive test for a drug or drug metabolite, an adulterated test, or a substituted test pertaining to the employee.
 - (1) For this purpose, the concerned DOT agency is the one whose drug and alcohol testing rules apply to the majority of the covered employees in your organization. The concerned DOT agency uses its applicable procedures for considering requests for waivers.
 - (2) Before taking action on a waiver request, the concerned DOT agency coordinates with other DOT agencies that regulate the employer's other covered employees.
 - (3) The concerned DOT agency provides a written response to each employer that petitions for a waiver, setting forth the reasons for the agency's decision on the waiver request.
- (c) Your request for a waiver must include, as a minimum, the following elements:
 - (1) Information about your organization:
 - (i) Your determination that standing employees down is necessary for safety in your organization and a statement of your basis for it, including any data on safety problems or incidents that could have been

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- prevented if a stand-down procedure had been in place;
 - (ii) Data showing the number of confirmed laboratory positive, adulterated, and substituted test results for your employees over the two calendar years preceding your waiver request, and the number and percentage of those test results that were verified positive, adulterated, or substituted by the MRO;
 - (iii) Information about the work situation of the employees subject to stand-down, including a description of the size and organization of the unit(s) in which the employees work, the process through which employees will be informed of the stand-down, whether there is an in-house MRO, and whether your organization has a medical disqualification or stand-down policy for employees in situations other than drug and alcohol testing; and
 - (iv) A statement of which DOT agencies regulate your employees.
- (2) Your proposed written company policy concerning stand-down, which must include the following elements:
- (i) Your assurance that you will distribute copies of your written policy to all employees that it covers;
 - (ii) Your means of ensuring that no information about the confirmed positive, adulterated, or substituted test result or the reason for the employee's temporary removal from performance of safety-sensitive functions becomes available, directly or indirectly, to anyone in your organization (or subsequently to another employer) other than the employee, the MRO and the DER;
 - (iii) Your means of ensuring that all covered employees in a particular job category in your organization are treated the same way with respect to stand-down;
 - (iv) Your means of ensuring that a covered employee will be subject to stand-down only with respect to the actual performance of safety-sensitive duties;
 - (v) Your means of ensuring that you will not take any action adversely affecting the employee's pay and benefits pending the completion of the MRO's verification process. This includes continuing to pay the employee during the period of the stand-down in the same way you would have paid him or her had he or she not been stood down;
 - (vi) Your means of ensuring that the verification process will commence no later than the time an employee is temporarily removed from the performance of safety-sensitive functions and that the period of stand-down for any employee will not exceed five days, unless you are informed in writing by the MRO that a longer period is needed to complete the verification process; and

- (vii) Your means of ensuring that, in the event that the MRO verifies the test negative or cancels it—
 - (A) You return the employee immediately to the performance of safety-sensitive duties;
 - (B) The employee suffers no adverse personnel or financial consequences as a result; and
 - (C) You maintain no individually identifiable record that the employee had a confirmed laboratory positive, adulterated, or substituted test result (i.e., you maintain a record of the test only as a negative or cancelled test).
- (d) The Administrator of the concerned DOT agency, or his or her designee, may grant a waiver request only if he or she determines that, in the context of your organization, there is a high probability that the procedures you propose will effectively enhance safety and protect the interests of employees in fairness and confidentiality.
 - (1) The Administrator, or his or her designee, may impose any conditions he or she deems appropriate on the grant of a waiver.
 - (2) The Administrator, or his or her designee, may immediately suspend or revoke the waiver if he or she determines that you have failed to protect effectively the interests of employees in fairness and confidentiality, that you have failed to comply with the requirements of this section, or that you have failed to comply with any other conditions the DOT agency has attached to the waiver.
- (e) You must not stand employees down in the absence of a waiver, or inconsistent with the terms of your waiver. If you do, you are in violation of this part and DOT agency drug testing regulations, and you are subject to enforcement action by the DOT agency just as you are for other violations of this part and DOT agency rules.

**§ 40.23
What actions do employers take after receiving verified test results?**

- a) As an employer who receives a verified positive drug test result, you must immediately remove the employee involved from performing safety-sensitive functions. You must take this action upon receiving the initial report of the verified positive test result. Do not wait to receive the written report or the result of a split specimen test.
- (b) As an employer who receives a verified adulterated or substituted drug test result, you must consider this a refusal to test and immediately remove the employee involved from performing safety-sensitive functions. You must take this action on receiving the initial report of the verified adulterated or substituted test result. Do not wait to receive the written report or the result of a split specimen test.
- (c) As an employer who receives an alcohol test result of 0.04 or higher, you must immediately remove the employee involved from performing safety-sensitive functions. If you receive an alcohol test result of 0.02—0.039, you must temporarily remove the employee involved from performing

- safety-sensitive functions, as provided in applicable DOT agency regulations. Do not wait to receive the written report of the result of the test.
 - (d) As an employer, when an employee has a verified positive, adulterated, or substituted test result, or has otherwise violated a DOT agency drug and alcohol regulation, you must not return the employee to the performance of safety-sensitive functions until or unless the employee successfully completes the return-to-duty process of Subpart O of this part.
 - (e) As an employer who receives a drug test result indicating that the employee's specimen was dilute, take action as provided in §40.197.
 - (f) As an employer who receives a drug test result indicating that the employee's urine specimen was cancelled because it was invalid and that a second collection must take place under direct observation—
 - (1) You must immediately direct the employee to provide a new specimen under direct observation.
 - (2) You must not attach consequences to the finding that the test was invalid other than collecting a new specimen under direct observation.
 - (3) You must not give any advance notice of this test requirement to the employee.
 - (4) You must instruct the collector to note on the CCF the same reason (e.g. random test, post-accident test) and DOT Agency (e.g., check DOT and FMCSA) as for the original collection.
 - (5) You must ensure that the collector conducts the collection under direct observation.
 - (g) As an employer who receives a cancelled test result when a negative result is required (e.g., pre-employment, return-to-duty, or follow-up test), you must direct the employee to provide another specimen immediately.
 - (h) As an employer, you may also be required to take additional actions required by DOT agency regulations (e.g., FAA rules require some positive drug tests to be reported to the Federal Air Surgeon).
 - (i) As an employer, you must not alter a drug or alcohol test result transmitted to you by an MRO, BAT, or C/TPA.
- [65 FR 79526, Dec. 19, 2000, as amended at 71 FR 49384, Aug. 23, 2006; 73 FR 35970, June 25, 2008; September 27, 2010]
- § 40.25
Must an employer check on the drug and alcohol testing record of employees it is intending to use to perform safety-sensitive duties?**
- (a) Yes, as an employer, you must, after obtaining an employee's written consent, request the information about the employee listed in paragraph (b) of this section. This requirement applies only to employees seeking to begin performing safety-sensitive duties for you for the first time (i.e., a new hire, an employee transfers into a safety-sensitive position). If the employee refuses to provide this written consent, you must not permit the employee to perform safety-sensitive functions.

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- (b) You must request the information listed in this paragraph (b) from DOT-regulated employers who have employed the employee during any period during the two years before the date of the employee's application or transfer:
 - (1) Alcohol tests with a result of 0.04 or higher alcohol concentration;
 - (2) Verified positive drug tests;
 - (3) Refusals to be tested (including verified adulterated or substituted drug test results);
 - (4) Other violations of DOT agency drug and alcohol testing regulations; and
 - (5) With respect to any employee who violated a DOT drug and alcohol regulation, documentation of the employee's successful completion of DOT return-to-duty requirements (including follow-up tests). If the previous employer does not have information about the return-to-duty process (e.g., an employer who did not hire an employee who tested positive on a pre-employment test), you must seek to obtain this information from the employee.
- (c) The information obtained from a previous employer includes any drug or alcohol test information obtained from previous employers under this section or other applicable DOT agency regulations.
- (d) If feasible, you must obtain and review this information before the employee first performs safety-sensitive functions. If this is not feasible, you must obtain and review the information as soon as possible. However, you must not permit the employee to perform safety-sensitive functions after 30 days from the date on which the employee first performed safety-sensitive functions, unless you have obtained or made and documented a good faith effort to obtain this information.
- (e) If you obtain information that the employee has violated a DOT agency drug and alcohol regulation, you must not use the employee to perform safety-sensitive functions unless you also obtain information that the employee has subsequently complied with the return-to-duty requirements of Subpart O of this part and DOT agency drug and alcohol regulations.
- (f) You must provide to each of the employers from whom you request information under paragraph (b) of this section written consent for the release of the information cited in paragraph (a) of this section.
- (g) The release of information under this section must be in any written form (e.g., fax, e-mail, letter) that ensures confidentiality. As the previous employer, you must maintain a written record of the information released, including the date, the party to whom it was released, and a summary of the information provided.
- (h) If you are an employer from whom information is requested under paragraph (b) of this section, you must, after reviewing the employee's specific, written consent, immediately release the requested information to the employer making the inquiry.

- (i) As the employer requesting the information required under this section, you must maintain a written, confidential record of the information you obtain or of the good faith efforts you made to obtain the information. You must retain this information for three years from the date of the employee's first performance of safety-sensitive duties for you.
- (j) As the employer, you must also ask the employee whether he or she has tested positive, or refused to test, on any pre-employment drug or alcohol test administered by an employer to which the employee applied for, but did not obtain, safety-sensitive transportation work covered by DOT agency drug and alcohol testing rules during the past two years. If the employee admits that he or she had a positive test or a refusal to test, you must not use the employee to perform safety-sensitive functions for you, until and unless the employee documents successful completion of the return-to-duty process (see paragraphs (b)(5) and (e) of this section).

**§ 40.26
What form must an employer use to report Management Information System (MIS) data to a DOT agency?**

As an employer, when you are required to report MIS data to a DOT agency, you must use the form and instructions at appendix H to part 40. You must submit the MIS report in accordance with rule requirements (e.g., dates for submission; selection of companies required to submit, and method of reporting) established by the DOT agency regulating your operation. [68 FR 43952, July 25, 2003]

**§ 40.27
May an employer require an employee to sign a consent or release in connection with the DOT drug and alcohol testing program?**

No, as an employer, you must not require an employee to sign a consent, release, waiver of liability, or indemnification agreement with respect to any part of the drug or alcohol testing process covered by this part (including, but not limited to, collections, laboratory testing, MRO and SAP services). [66 FR 41950, Aug. 9, 2001]

**§ 40.28
Where is other information on employer responsibilities found in this regulation?**

You can find other information on the responsibilities of employers in the following sections of this part:

- §40.3 Definition.
- §40.35 Information about DERs that employers must provide collectors.
- §40.45 Modifying CCFs, Use of foreign-language CCFs.
- §40.47 Use of non-Federal forms for DOT tests or Federal CCFs for non-DOT tests.
- §40.67 Requirements for direct observation.
- §§40.103–40.105 Blind specimen requirements.
- §40.173 Responsibility to ensure test of split specimen.

- §40.193 Action in "shy bladder" situations.
 - §40.197 Actions following report of a dilute specimen.
 - §40.207 Actions following a report of a cancelled drug test.
 - §40.209 Actions following and consequences of non-fatal flaws in drug tests.
 - §40.215 Information about DERs that employers must provide BATs and STTs.
 - §40.225 Modifying ATFs; use of foreign-language ATFs.
 - §40.227 Use of non-DOT forms for DOT tests or DOT ATFs for non-DOT tests.
 - §40.235 (c) and (d) responsibility to follow instructions for ASDs.
 - §40.255 (b) receipt and storage of alcohol test information.
 - §40.265 (c)–(e) actions in "shy lung" situations.
 - §40.267 Cancellation of alcohol tests.
 - §40.271 Actions in "correctable flaw" situations in alcohol tests.
 - §40.273 Actions following cancelled tests in alcohol tests.
 - §40.275 Actions in "non-fatal flaw" situations in alcohol tests.
 - §§40.287–40.289 Responsibilities concerning SAP services.
 - §§40.295–40.297 Prohibition on seeking second SAP evaluation or changing SAP recommendation.
 - §40.303 Responsibilities concerning aftercare recommendations.
 - §40.305 Responsibilities concerning return-to-duty decision.
 - §40.309 Responsibilities concerning follow-up tests.
 - §40.321 General confidentiality requirement.
 - §40.323 Release of confidential information in litigation.
 - §40.331 Other circumstances for the release of confidential information.
 - §40.333 Record retention requirements.
 - §40.345 Choice of who reports drug testing information to employers.
- [65 FR 79526, Dec. 19, 2000. Redesignated at 66 FR 41950, Aug. 9, 2001]

Subpart C - Urine Collection Personnel

**Subpart D
Collection Sites, Forms, Equipment and Supplies Used in DOT Urine Collections**

**§ 40.47
May employers use the CCF for non-Federal collections or non-Federal forms for DOT collections?**

- (a) No, as an employer, you are prohibited from using the CCF for non-Federal urine collections. You are also prohibited from using non-Federal forms for DOT urine collections. Doing either subjects you to enforcement action under DOT agency regulations.
- (b) (1) In the rare case where the collector, either by mistake or as the only means to

conduct a test under difficult circumstances (e.g., post-accident or reasonable suspicion test with insufficient time to obtain the CCF), uses a non-Federal form for a DOT collection, the use of a non-Federal form does not present a reason for the laboratory to reject the specimen for testing or for an MRO to cancel the result.

- (2) The use of the non-Federal form is a "correctable flaw." As an MRO, to correct the problem you must follow the procedures of §40.205(b) (2).

[65 FR 79526, Dec. 19, 2000, as amended at 66 FR 41950, Aug. 9, 2001]

Subpart E - Urine Specimen Collections

§ 40.67

When and how is a directly observed collection conducted?

- (a) As an employer, you must direct an immediate collection under direct observation with no advance notice to the employee, if:
 - (1) The laboratory reported to the MRO that a specimen is invalid, and the MRO reported to you that there was not an adequate medical explanation for the result;
 - (2) The MRO reported to you that the original positive, adulterated, or substituted result had to be cancelled because the test of the split specimen could not be performed; or
 - (3) The laboratory reported to the MRO that the specimen was negative-dilute with a creatinine concentration greater than or equal to 2 mg/dL but less than or equal to 5 mg/dL, and the MRO reported the specimen to you as negative-dilute and that a second collection must take place under direct observation (see §40.197(b)(1)).
- (b) As an employer, you must direct a collection under direct observation of an employee if the drug test is a return-to-duty test or a follow-up test.
- (c) As a collector, you must immediately conduct a collection under direct observation if:
 - (1) You are directed by the DER to do so (see paragraphs (a) and (b) of this section); or
 - (2) You observed materials brought to the collection site or the employee's conduct clearly indicates an attempt to tamper with a specimen (see §§40.61(f)(5)(i) and 40.63(e)); or
 - (3) The temperature on the original specimen was out of range (see §40.65(b)(5)); or (4) The original specimen appeared to have been tampered with (see §40.65(c)(1)).
- (d)(1) As the employer, you must explain to the employee the reason for a directly observed collection under paragraph (a) or (b) of this section.
- (2) As the collector, you must explain to the employee the reason, if known, under this part for a directly observed

collection under paragraphs (c)(1) through (3) of this section.

- (e) As the collector, you must complete a new CCF for the directly observed collection.
 - 1) You must mark the "reason for test" block (Step 1) the same as for the first collection.
 - 2) You must check the "Observed, (Enter Remark)" box and enter the reason (see §40.67(b)) in the "Remarks" line (Step 2).
- (f) In a case where two sets of specimens are being sent to the laboratory because of suspected tampering with the specimen at the collection site, enter on the "Remarks" line of the CCF (Step 2) for each specimen a notation to this effect (e.g., collection 1 of 2, or 2 of 2) and the specimen ID number of the other specimen.
- (g) As the collector, you must ensure that the observer is the same gender as the employee. You must never permit an opposite gender person to act as the observer. The observer can be a different person from the collector and need not be a qualified collector.
- (h) As the collector, if someone else is to observe the collection (e.g., in order to ensure a same gender observer), you must verbally instruct that person to follow procedures at paragraphs (i) and (j) of this section. If you, the collector, are the observer, you too must follow these procedures.
- (i) As the observer, you must request the employee to raise his or her shirt, blouse, or dress/skirt, as appropriate, above the waist; and lower clothing and underpants to show you, by turning around, that they do not have a prosthetic device. After you have determined that the employee does not have such a device, you may permit the employee to return clothing to its proper position for observed urination.
- (j) As the observer, you must watch the employee urinate into the collection container. Specifically, you are to watch the urine go from the employee's body into the collection container.
- (k) As the observer but not the collector, you must not take the collection container from the employee, but you must observe the specimen as the employee takes it to the collector.
 - (l) As the collector, when someone else has acted as the observer, you must include the observer's name in the "Remarks" line of the CCF (Step 2).
 - (m) As the employee, if you decline to allow a directly observed collection required or permitted under this section to occur, this is a refusal to test.
 - (n) As the collector, when you learn that a directly observed collection should have been collected but was not, you must inform the employer that it must direct the employee to have an immediate recollection under direct observation.

[65 FR 79526, Dec. 19, 2000, as amended at 66 FR 41950, Aug. 9, 2001; 68 FR 31626, May 28, 2003; 69 FR 64867, Nov.9, 2004; 73 FR 35970, June 25, 2008; 73 FR 70283, November 20, 2008; 74 FR 37949, July 30, 2009]

§ 40.69

How is a monitored collection conducted?

- (a) As the collector, you must secure the room being used for the monitored collection so that no one except the employee and the monitor can enter it until after the collection has been completed.
- (b) As the collector, you must ensure that the monitor is the same gender as the employee, unless the monitor is a medical professional (e.g., nurse, doctor, physician's assistant, technologist, or technician licensed or certified to practice in the jurisdiction in which the collection takes place). The monitor can be a different person from the collector and need not be a qualified collector.
- (c) As the collector, if someone else is to monitor the collection (e.g., in order to ensure a same-gender monitor), you must verbally instruct that person to follow the procedures of paragraphs (d) and (e) of this section. If you, the collector, are the monitor, you must follow these procedures.
- (d) As the monitor, you must not watch the employee urinate into the collection container. If you hear sounds or make other observations indicating an attempt to tamper with a specimen, there must be an additional collection under direct observation (see §§40.63(e), 40.65(c), and 40.67(b)).
- (e) As the monitor, you must ensure that the employee takes the collection container directly to the collector as soon as the employee has exited the enclosure.
- (f) As the collector, when someone else has acted as the monitor, you must note that person's name in the "Remarks" line of the CCF (Step 2).
- (g) As the employee being tested, if you decline to permit a collection authorized under this section to be monitored, it is a refusal to test.

[65 FR 79526, Dec. 19, 2000, as amended at 66 FR 41951, Aug. 9, 2001]

Subpart F - Drug Testing Laboratories

§ 40.81

What laboratories may be used for DOT drug testing?

- (a) As a drug testing laboratory located in the U.S., you are permitted to participate in DOT drug testing only if you are certified by HHS under the National Laboratory Certification Program (NLCP) for all testing required under this part.
- (b) As a drug testing laboratory located in Canada or Mexico which is not certified by HHS under the NLCP, you are permitted to participate in DOT drug testing only if:
 - (1) The DOT, based on a written recommendation from HHS, has approved your laboratory as meeting HHS laboratory certification standards or deemed your laboratory fully equivalent to a laboratory meeting HHS laboratory certification standards for all testing required under this part; or
 - (2) The DOT, based on a written recommendation from HHS, has

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- recognized a Canadian or Mexican certifying organization as having equivalent laboratory certification standards and procedures to those of HHS, and the Canadian or Mexican certifying organization has certified your laboratory under those equivalent standards and procedures.
- (c) As a laboratory participating in the DOT drug testing program, you must comply with the requirements of this part. You must also comply with all applicable requirements of HHS in testing DOT specimens, whether or not the HHS requirements are explicitly stated in this part.
 - (d) If DOT determines that you are in noncompliance with this part, you could be subject to PIE proceedings under Subpart R of this part. If the Department issues a PIE with respect to you, you are ineligible to participate in the DOT drug testing program even if you continue to meet the requirements of paragraph (a) or (b) of this section.

**§ 40.83
How do laboratories process incoming specimens?**

As the laboratory, you must do the following when you receive a DOT specimen:

- (a) You are authorized to receive only Copy 1 of the CCF. You are not authorized to receive other copies of the CCF or any copies of the alcohol testing form.
- (b) You must comply with applicable provisions of the HHS Guidelines concerning accessioning and processing urine drug specimens.
- (c) You must inspect each specimen and CCF for the following "fatal flaws":
 - (1) The specimen ID numbers on the specimen bottle and the CCF do not match;
 - (2) The specimen bottle seal is broken or shows evidence of tampering, unless a split specimen can be redesignated (see paragraph (h) of this section);
 - (3) The collector's printed name and signature are omitted from the CCF; and
 - (4) There is an insufficient amount of urine in the primary bottle for analysis, unless the specimens can be redesignated (see paragraph (h) of this section).
- (d) When you find a specimen meeting the criteria of paragraph (c) of this section, you must document your findings and stop the testing process. Report the result in accordance with §40.97(a)(3).

- (e) You must inspect each CCF for the presence of the collector's signature on the certification statement in Step 4 of the CCF. Upon finding that the signature is omitted, document the flaw and continue the testing process.
 - (1) In such a case, you must retain the specimen for a minimum of 5 business days from the date on which you initiated action to correct the flaw.
 - (2) You must then attempt to correct the flaw by following the procedures of §40.205(b)(1).
 - (3) If the flaw is not corrected, report the result as rejected for testing in accordance with §40.97(a)(3).
- (f) If you determine that the specimen temperature was not checked and the "Remarks" line did not contain an entry regarding the temperature being outside of range, you must then attempt to correct the problem by following the procedures of §40.208.
 - (1) In such a case, you must continue your efforts to correct the problem for five business days, before you report the result.
 - (2) When you have obtained the correction, or five business days have elapsed, report the result in accordance with §40.97(a).
- (g) If you determine that a CCF that fails to meet the requirements of §40.45(a) (e.g., a non-Federal form or an expired Federal form was used for the collection), you must attempt to correct the use of the improper form by following the procedures of §40.205(b) (2).
 - (1) In such a case, you must retain the specimen for a minimum of 5 business days from the date on which you initiated action to correct the problem.
 - (2) If the problem(s) is not corrected, you must reject the test and report the result in accordance with §40.97(a)(3).
- (h) If the CCF is marked indicating that a split specimen collection was collected and if the split specimen does not accompany the primary, has leaked, or is otherwise unavailable for testing, you must still test the primary specimen and follow appropriate procedures outlined in §40.175(b) regarding the unavailability of the split specimen for testing.
 - (1) The primary specimen and the split specimen can be redesignated (i.e., Bottle B is redesignated as Bottle A, and vice-versa) if:

- (i) The primary specimen appears to have leaked out of its sealed bottle and the laboratory believes a sufficient amount of urine exists in the split specimen to conduct all appropriate primary laboratory testing; or
 - (ii) The primary specimen is labeled as Bottle B, and the split specimen as Bottle A; or
 - (iii) The laboratory opens the split specimen instead of the primary specimen, the primary specimen remains sealed, and the laboratory believes a sufficient amount of urine exists in the split specimen to conduct all appropriate primary laboratory testing; or
 - (iv) The primary specimen seal is broken but the split specimen remains sealed and the laboratory believes a sufficient amount of urine exists in the split specimen to conduct all appropriate primary laboratory testing.
- (2) In situations outlined in paragraph (g)(1) of this section, the laboratory shall mark through the "A" and write "B," then initial and date the change. A corresponding change shall be made to the other bottle by marking through the "B" and writing "A," and initialing and dating the change.
- (i) A notation shall be made on Copy 1 of the CCF (Step 5a) and on any laboratory internal chain of custody documents, as appropriate, for any fatal or correctable flaw.

[65 FR 79526, Dec. 19, 2000, as amended at 66 FR 41951, Aug. 9, 2001; 71 FR 49384, Aug. 23, 2006; 73 FR 35970, June 25, 2008; 75 FR 59107, September 27, 2010]

**§ 40.85
What drugs do laboratories test for?**

As a laboratory, you must test for the following five drugs or classes of drugs in a DOT drug test. You must not test "DOT specimens" for any other drugs.

- (a) Marijuana metabolites.
- (b) Cocaine metabolites.
- (c) Amphetamines.
- (d) Opiate metabolites.
- (e) Phencyclidine (PCP).

**§ 40.87
What are the cutoff concentrations for drug tests?**

- (a) As a laboratory, you must use the cutoff concentrations displayed in the following table for initial and confirmation drug tests. All cutoff concentrations are expressed in nanograms per milliliter (ng/mL). The table follows:

Initial test analyte	Initial test cutoff concentration	Confirmatory test analyte	Confirmatory test cutoff concentration
Marijuana metabolites	50 ng/mL	THCA ¹	15 ng/mL
Cocaine metabolites	150 ng/mL	Benzoyllecgonine	100 ng/mL
Opiate metabolites			

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Codeine / Morphine ²	2,000 ng/mL	Codeine	2,000 ng/mL
		Morphine	2,000 ng/mL
6-Acetylmorphine	10 ng/mL	6-Acetylmorphine	10 ng/mL
Phencyclidine	25 ng/mL	Phencyclidine	25 ng/mL
Amphetamines ³			
AMP/MAMP ⁴	500 ng/mL	Amphetamine	250 ng/mL
		Methamphetamine ⁵	250 ng/mL
MDMA ⁶	500 ng/mL	MDMA	250 ng/mL
		MDA ⁷	250 ng/mL
		MDEA ⁸	250 ng/mL

- ¹ Delta-9-tetrahydrocannabinol-9-carboxylic acid (THCA).
- ² Morphine is the target analyte for codeine/morphine testing.
- ³ Either a single initial test kit or multiple initial test kits may be used provided the single test kit detects each target analyte independently at the specified cutoff.
- ⁴ Methamphetamine is the target analyte for amphetamine/methamphetamine testing.
- ⁵ To be reported positive for methamphetamine, a specimen must also contain amphetamine at a concentration equal to or greater than 100 ng/mL.
- ⁶ Methylenedioxymethamphetamine (MDMA).
- ⁷ Methylenedioxyamphetamine (MDA).
- ⁸ Methylenedioxyethylamphetamine (MDEA)

- (b) On an initial drug test, you must report a result below the cutoff concentration as negative. If the result is at or above the cutoff concentration, you must conduct a confirmation test.
- (c) On a confirmation drug test, you must report a result below the cutoff concentration as negative and a result at or above the cutoff concentration as confirmed positive.
- (d) You must report quantitative values for morphine or codeine at 15,000 ng/mL or above.
[65 FR 79526, Dec. 19, 2000, as amended at 75 FR 49862, August 16, 2010; FR 26473, May 4, 2012]

§ 40.89
What is validity testing, and are laboratories required to conduct it?

- (a) Specimen validity testing is the evaluation of the specimen to determine if it is consistent with normal human urine. The purpose of validity testing is to determine whether certain adulterants or foreign substances were added to the urine, if the urine was diluted, or if the specimen was substituted.
- (b) As a laboratory, you must conduct validity testing.

[65 FR 79526, Dec. 19, 2000, as amended at 66 FR 41951, Aug. 9, 2001, 73 FR 35970, June 25, 2008]

§ 40.97
What do laboratories report and how do they report it?

- (a) As a laboratory, you must report the results for each primary specimen. The result of a primary specimen will fall into one of the following three categories. However, as a laboratory, you must report the actual results (and not the categories):
 - (1) Category 1: Negative Results. As a laboratory, when you find a specimen to be negative, you must report the test result as being one of the following, as appropriate:
 - (i) Negative, or
 - (ii) Negative-dilute, with numerical values for creatinine and specific gravity.
 - (2) Category 2: Non-negative Results. As a laboratory, when you find a specimen to

be non-negative, you must report the test result as being one or more of the following, as appropriate:

- (i) Positive, with drug(s)/metabolite(s) noted, with numerical values for the drug(s) or drug metabolites(s).
- (ii) Positive-dilute, with drug(s)/metabolite(s) noted, with numerical values for the drug(s) or drug metabolite(s) and with numerical values for creatinine and specific gravity;
- (iii) Adulterated, with adulterant(s) noted, with confirmatory test values (when applicable), and with remark(s);
- (iv) Substituted, with confirmatory test values for creatinine and specific gravity; or
- (v) Invalid result, with remark(s).
Laboratories will report actual values for pH results
- (3) Category 3: Rejected for Testing. As a laboratory, when you reject a specimen for testing, you must report the result as being Rejected for Testing, with remark(s).
- (b) As a laboratory, you must report laboratory results directly, and only, to the MRO at his or her place of business. You must not report results to or through the DER or a service agent (e.g., C/TPA).
 - (1) Negative results: You must fax, courier, mail, or electronically transmit a legible image or copy of the fully-completed Copy 1 of the CCF which has been signed by the certifying scientist, or you

may provide the laboratory results report electronically (i.e., computer data file).

- (i) If you elect to provide the laboratory results report, you must include the following elements, as a minimum, in the report format:
 - (A) Laboratory name and address;
 - (B) Employer's name (you may include I.D. or account number);
 - (C) Medical review officer's name;
 - (D) Specimen I.D. number;
 - (E) Donor's SSN or employee I.D. number, if provided;
 - (F) Reason for test, if provided;
 - (G) Collector's name and telephone number;
 - (H) Date of the collection;
 - (I) Date received at the laboratory;
 - (J) Date certifying scientist released the results;
 - (K) Certifying scientist's name;
 - (L) Results (e.g., positive, adulterated) as listed in paragraph (a) of this section; and
 - (M) Remarks section, with an explanation of any situation in which a correctable flaw has been corrected.
- (ii) You may release the laboratory results report only after review and approval by the certifying scientist. It must reflect the same test result information as contained on the CCF signed by the certifying scientist. The information contained in the laboratory results

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report may not contain information that does not appear on the CCF.

- (iii) The results report may be transmitted through any means that ensures accuracy and confidentiality. You, as the laboratory, together with the MRO, must ensure that the information is adequately protected from unauthorized access or release, both during transmission and in storage.
- (2) **Non-negative and Rejected for Testing results:** You must fax, courier, mail, or electronically transmit a legible image or copy of the fully-completed Copy 1 of the CCF that has been signed by the certifying scientist. In addition, you may provide the electronic laboratory results report following the format and procedures set forth in paragraphs (b)(1)(i) and (ii) of this section.
- (c) In transmitting laboratory results to the MRO, you, as the laboratory, together with the MRO, must ensure that the information is adequately protected from unauthorized access or release, both during transmission and in storage. If the results are provided by fax, the fax connection must have a fixed telephone number accessible only to authorized individuals.
- (d) You must transmit test results to the MRO in a timely manner, preferably the same day that review by the certifying scientist is completed.
- (e) (1) You must provide quantitative values for confirmed positive drug test results to the MRO.
(2) You must provide numerical values that support the adulterated (when applicable) or substituted result, without a request from the MRO.
(3) You must also provide the MRO numerical values for creatinine and specific gravity for the negative-dilute test result, without a request from the MRO.
- (f) You must provide quantitative values for confirmed opiate results for morphine or codeine at 15,000 ng/mL or above, even if the MRO has not requested quantitative values for the test result.

[65 FR 79526, Dec. 19, 2000, as amended at 66 FR 41951, Aug. 9, 2001; 68 FR 31626, May 28, 2003; 69 FR 64867, Nov. 9, 2004, 73 FR 35970, June 25, 2008; 75 FR 59107, 75 FR 49862, August 16, 2010; September 27, 2010, 77 FR 26473, May 4, 2012]

Subpart G - Medical Review Officers and the Verification Process

§ 40.131

How does the MRO or DER notify an employee of the verification process after receiving laboratory confirmed non-negative test results?

- (a) When, as the MRO, you receive a confirmed positive, adulterated, substituted, or invalid test result from the laboratory, you must contact the employee directly (i.e., actually talk to the employee), on a confidential basis, to determine whether the

employee wants to discuss the test result. In making this contact, you must explain to the employee that, if he or she declines to discuss the result, you will verify the test as positive or as a refusal to test because of adulteration or substitution, as applicable.

- (b) As the MRO, staff under your personal supervision may conduct this initial contact for you.
 - (1) This staff contact must be limited to scheduling the discussion between you and the employee and explaining the consequences of the employee's declining to speak with you (i.e., that the MRO will verify the test without input from the employee). If the employee declines to speak with you, the staff person must document the employee's decision, including the date and time.
 - (2) A staff person must not gather any medical information or information concerning possible explanations for the test result.
 - (3) A staff person may advise an employee to have medical information (e.g., prescriptions, information forming the basis of a legitimate medical explanation for a confirmed positive test result) ready to present at the interview with the MRO.
 - (4) Since you are required to speak personally with the employee, face-to-face or on the phone, your staff must not inquire if the employee wishes to speak with you.
- (c) As the MRO, you or your staff must make reasonable efforts to reach the employee at the day and evening telephone numbers listed on the CCF. Reasonable efforts include, as a minimum, three attempts, spaced reasonably over a 24-hour period, to reach the employee at the day and evening telephone numbers listed on the CCF. If you or your staff cannot reach the employee directly after making these efforts, you or your staff must take the following steps:
 - (1) Document the efforts you made to contact the employee, including dates and times. If both phone numbers are incorrect (e.g., disconnected, wrong number), you may take the actions listed in paragraph (c)(2) of this section without waiting the full 24-hour period.
 - (2) Contact the DER, instructing the DER to contact the employee.
 - (i) You must simply direct the DER to inform the employee to contact you.
 - (ii) You must not inform the DER that the employee has a confirmed positive, adulterated, substituted, or invalid test result.
 - (iii) You must document the dates and times of your attempts to contact the DER, and you must document the name of the DER you contacted and the date and time of the contact.
 - (d) As the DER, you must attempt to contact the employee immediately, using procedures that protect, as much as possible, the confidentiality of the MRO's request that the employee contact the MRO. If you successfully contact the employee (i.e., actually talk to the employee), you must document the date and time of the

contact, and inform the MRO. You must inform the employee that he or she should contact the MRO immediately. You must also inform the employee of the consequences of failing to contact the MRO within the next 72 hours (see §40.133(a)(2)).

- (1) As the DER, you must not inform anyone else working for the employer that you are seeking to contact the employee on behalf of the MRO.
- (2) If, as the DER, you have made all reasonable efforts to contact the employee but failed to do so, you may place the employee on temporary medically unqualified status or medical leave. Reasonable efforts include, as a minimum, three attempts, spaced reasonably over a 24-hour period, to reach the employee at the day and evening telephone numbers listed on the CCF.
 - (i) As the DER, you must document the dates and times of these efforts.
 - (ii) If, as the DER, you are unable to contact the employee within this 24-hour period, you must leave a message for the employee by any practicable means (e.g., voice mail, e-mail, letter) to contact the MRO and inform the MRO of the date and time of this attempted contact.

[65 FR 79526, Dec. 19, 2000, as amended at 66 FR 41952, Aug. 9, 2001; 68 FR 31626, May 28, 2003; 69 FR 64867, Nov. 9, 2004; 73 FR 35971, June 25, 2008]

§ 40.135

What does the MRO tell the employee at the beginning of the verification interview?

- (a) As the MRO, you must tell the employee that the laboratory has determined that the employee's test result was positive, adulterated, substituted, or invalid, as applicable. You must also tell the employee of the drugs for which his or her specimen tested positive, or the basis for the finding of adulteration or substitution.
- (b) You must explain the verification interview process to the employee and inform the employee that your decision will be based on information the employee provides in the interview.
- (c) You must explain that, if further medical evaluation is needed for the verification process, the employee must comply with your request for this evaluation and that failure to do so is equivalent of expressly declining to discuss the test result.
- (d) As the MRO, you must warn an employee who has a confirmed positive, adulterated, substituted or invalid test that you are required to provide to third parties drug test result information and medical information affecting the performance of safety-sensitive duties that the employee gives you in the verification process without the employee's consent (see §40.327).
 - (1) You must give this warning to the employee before obtaining any medical information as part of the verification process.
 - (2) For purposes of this paragraph (d), medical information includes

information on medications or other substances affecting the performance of safety-sensitive duties that the employee reports using or medical conditions the employee reports having.

- (3) For purposes of this paragraph (d), the persons to whom this information may be provided include the employer, a SAP evaluating the employee as part of the return to duty process (see §40.293(g)), DOT, another Federal safety agency (e.g., the NTSB), or any state safety agency as required by state law.
- (e) You must also advise the employee that, after informing any third party about any medication the employee is using pursuant to a legally valid prescription under the Controlled Substances Act, you will allow 5 days for the employee to have the prescribing physician contact you to determine if the medication can be changed to one that does not make the employee medically unqualified or does not pose a significant safety risk. If, as an MRO, you receive such information from the prescribing physician, you must transmit this information to any third party to whom you previously provided information about the safety risks of the employee's other medication.

[65 FR 79526, Dec. 19, 2000, as amended at 66 FR 41952, Aug. 9, 2001]

§ 40.163

How does the MRO report drug test results?

- (a) As the MRO, it is your responsibility to report all drug test results to the employer.
- (b) You may use a signed or stamped and dated legible photocopy of Copy 2 of the CCF to report test results.
- (c) If you do not report test results using Copy 2 of the CCF for this purpose, you must provide a written report (e.g., a letter) for each test result. This report must, as a minimum, include the following information:
 - (1) Full name, as indicated on the CCF, of the employee tested;
 - (2) Specimen ID number from the CCF and the donor SSN or employee ID number;
 - (3) Reason for the test, if indicated on the CCF (e.g., random, post-accident);
 - (4) Date of the collection;
 - (5) Date you received Copy 2 of the CCF;
 - (6) Result of the test (i.e., positive, negative, dilute, refusal to test, test cancelled) and the date the result was verified by the MRO;
 - (7) For verified positive tests, the drug(s)/metabolite(s) for which the test was positive;
 - (8) For cancelled tests, the reason for cancellation; and
 - (9) For refusals to test, the reason for the refusal determination (e.g., in the case of an adulterated test result, the name of the adulterant).
- (d) As an exception to the reporting requirements of paragraph (b) and (c) of this section, the MRO may report negative results using an electronic data file.
 - (1) If you report negatives using an electronic data file, the report must contain, as a minimum, the information

specified in paragraph (c) of this section, as applicable for negative test results.

- (2) In addition, the report must contain your name, address, and phone number, the name of any person other than you reporting the results, and the date the electronic results report is released.
- (e) You must retain a signed or stamped and dated copy of Copy 2 of the CCF in your records. If you do not use Copy 2 for reporting results, you must maintain a copy of the signed or stamped and dated letter in addition to the signed or stamped and dated Copy 2. If you use the electronic data file to report negatives, you must maintain a retrievable copy of that report in a format suitable for inspection and auditing by a DOT representative.
- (f) You must not use Copy 1 of the CCF to report drug test results.
- (g) You must not provide quantitative values to the DER or C/TPA for drug or validity test results. However, you must provide the test information in your possession to a SAP who consults with you (see §40.293(g)).
- (h) You must maintain reports and records related to negatives and cancelled results for one year; you must maintain reports and records related to positives and refusals for five years, unless otherwise specified by applicable DOT agency regulations.

[66 FR 41952, Aug. 9, 2001, as amended 75 FR 49863; August 16, 2010; 75 FR 59107, September 27, 2010, 76 FR 59578, Sep 27, 2011]

§ 40.165

To whom does the MRO transmit reports of drug test results?

- (a) As the MRO, you must report all drug test results to the DER, except in the circumstances provided for in §40.345.
- (b) If the employer elects to receive reports of results through a C/TPA, acting as an intermediary as provided in §40.345, you must report the results through the designated C/TPA.

§ 40.167

How are MRO reports of drug results transmitted to the employer?

As the MRO or C/TPA who transmits drug test results to the employer, you must comply with the following requirements:

- (a) You must report the results in a confidential manner.
- (b) You must transmit to the DER on the same day the MRO verifies the result or the next business day all verified positive test results, results requiring an immediate collection under direct observation, adulterated or substituted specimen results, and other refusals to test.
 - (1) Direct telephone contact with the DER is the preferred method of immediate reporting. Follow up your phone call with appropriate documentation (see §40.163).
 - (2) You are responsible for identifying yourself to the DER, and the DER must have a means to confirm your identification.
 - (3) The MRO's report that you transmit to the employer must contain all of the information required by §40.163.

(c) You must transmit the MRO's report(s) of verified tests to the DER so that the DER receives it within two days of verification by the MRO.

- (1) You must fax, courier, mail, or electronically transmit a legible image or copy of either the signed or stamped and dated Copy 2 or the written report (see §40.163(b) and (c)).
- (2) Negative results reported electronically (i.e., computer data file) do not require an image of Copy 2 or the written report.
- (d) In transmitting test results, you or the C/TPA and the employer must ensure the security of the transmission and limit access to any transmission, storage, or retrieval systems.
- (e) MRO reports are not subject to modification or change by anyone other than the MRO, as provided in §40.149(c).

[65 FR 79526, Dec. 19, 2000, as amended at 66 FR 41953, Aug. 9, 2001]

§ 40.169

Where is other information concerning the role of MROs and the verification process found in this regulation?

You can find more information concerning the role of MROs in several sections of this part:

- §40.3 Definition.
- §§40.47–40.49 Correction of form and kit errors.
- §40.67 Role in direct observation and other atypical test situations.
- §40.83 Laboratory handling of fatal and correctable flaws.
- §40.97 Laboratory handling of test results and quantitative values.
- §40.99 Authorization of longer laboratory retention of specimens.
- §40.101 Relationship with laboratories; avoidance of conflicts of interest.
- §40.105 Notification of discrepancies in blind specimen results.
- §40.171 Request for test of split specimen.
- §40.187 Action concerning split specimen test results.
- §40.193 Role in “shy bladder” situations.
- §40.195 Role in cancelling tests.
- §40.199–40.203 Documenting errors in tests.
- §40.327 Confidentiality and release of information.
- §40.347 Transfer of records.
- §40.353 Relationships with service agents.

Subpart H - Split Specimen Tests

§ 40.171

How does an employee request a test of a split specimen?

- (a) As an employee, when the MRO has notified you that you have a verified positive drug test and/or refusal to test because of adulteration or substitution, you have 72 hours from the time of notification to request a test of the split specimen. The request may be verbal or in writing. If you make this request to the MRO within 72 hours, you trigger the requirements of this section for a test of the split specimen. There is no split specimen testing for an invalid result.
- (b) (1) If, as an employee, you have not requested a test of the split specimen

within 72 hours, you may present to the MRO information documenting that serious injury, illness, lack of actual notice of the verified test result, inability to contact the MRO (e.g., there was no one in the MRO's office and the answering machine was not working), or other circumstances unavoidably prevented you from making a timely request.

(2) As the MRO, if you conclude from the employee's information that there was a legitimate reason for the employee's failure to contact you within 72 hours, you must direct that the test of the split specimen take place, just as you would when there is a timely request.

(c) When the employee makes a timely request for a test of the split specimen under paragraphs (a) and (b) of this section, you must, as the MRO, immediately provide written notice to the laboratory that tested the primary specimen, directing the laboratory to forward the split specimen to a second HHS-certified laboratory. You must also document the date and time of the employee's request.

[65 FR 79526, Dec. 19, 2000, as amended at 73 FR 35973, June 25, 2008]

§ 40.173
Who is responsible for paying for the test of a split specimen?

- (a) As the employer, you are responsible for making sure (e.g., by establishing appropriate accounts with laboratories for testing split specimens) that the MRO, first laboratory, and second laboratory perform the functions noted in §§40.175–40.185 in a timely manner, once the employee has made a timely request for a test of the split specimen.
- (b) As the employer, you must not condition your compliance with these requirements on the employee's direct payment to the MRO or laboratory or the employee's agreement to reimburse you for the costs of testing. For example, if you ask the employee to pay for some or all of the cost of testing the split specimen, and the employee is unwilling or unable to do so, you must ensure that the test takes place in a timely manner, even though this means that you pay for it.
- (c) As the employer, you may seek payment or reimbursement of all or part of the cost of the split specimen from the employee (e.g., through your written company policy or a collective bargaining agreement). This part takes no position on who ultimately pays the cost of the test, so long as the employer ensures that the testing is conducted as required and the results released appropriately.

Subpart I—Problems in Drug Tests

§ 40.191
What is a refusal to take a DOT drug test, and what are the consequences?

- (a) As an employee, you have refused to take a drug test if you:
 - (1) Fail to appear for any test (except a pre-employment test) within a reasonable time, as determined by the employer, consistent with applicable DOT agency regulations, after being directed to do so by the employer. This includes the failure of an employee (including an owner-operator) to appear for a test when called by a C/TPA (see §40.61(a));
 - (2) Fail to remain at the testing site until the testing process is complete; Provided, That an employee who leaves the testing site before the testing process commences (see §40.63 (c)) for a pre-employment test is not deemed to have refused to test;
 - (3) Fail to provide a urine specimen for any drug test required by this part or DOT agency regulations; Provided, That an employee who does not provide a urine specimen because he or she has left the testing site before the testing process commences (see §40.63 (c)) for a pre-employment test is not deemed to have refused to test;
 - (4) In the case of a directly observed or monitored collection in a drug test, fail to permit the observation or monitoring of your provision of a specimen (see §§40.67(l) and 40.69(g));
 - (5) Fail to provide a sufficient amount of urine when directed, and it has been determined, through a required medical evaluation, that there was no adequate medical explanation for the failure (see §40.193(d)(2));
 - (6) Fail or decline to take an additional drug test the employer or collector has directed you to take (see, for instance, §40.197(b));
 - (7) Fail to undergo a medical examination or evaluation, as directed by the MRO as part of the verification process, or as directed by the DER under §40.193(d). In the case of a pre-employment drug test, the employee is deemed to have refused to test on this basis only if the pre-employment test is conducted following a contingent offer of employment. If there was no contingent offer of employment, the MRO will cancel the test; or
 - (8) Fail to cooperate with any part of the testing process (e.g., refuse to empty pockets when directed by the collector, behave in a confrontational way that disrupts the collection process, fail to wash hands after being directed to do so by the collector).
 - (9) For an observed collection, fail to follow the observer's instructions to raise your clothing above the waist, lower clothing and underpants, and to turn around to permit the observer to determine if you have any type of prosthetic or other device that could be used to interfere with the collection process.
 - (10) Possess or wear a prosthetic or other device that could be used to interfere with the collection process.
 - (11) Admit to the collector or MRO that you adulterated or substituted the specimen.

- (b) As an employee, if the MRO reports that you have a verified adulterated or substituted test result, you have refused to take a drug test.
- (c) As an employee, if you refuse to take a drug test, you incur the consequences specified under DOT agency regulations for a violation of those DOT agency regulations.
- (d) As a collector or an MRO, when an employee refuses to participate in the part of the testing process in which you are involved, you must terminate the portion of the testing process in which you are involved, document the refusal on the CCF (including, in the case of the collector, printing the employee's name on Copy 2 of the CCF), immediately notify the DER by any means (e.g., telephone or secure fax machine) that ensures that the refusal notification is immediately received. As a referral physician (e.g., physician evaluating a "shy bladder" condition or a claim of a legitimate medical explanation in a validity testing situation), you must notify the MRO, who in turn will notify the DER.
 - (1) As the collector, you must note the refusal in the "Remarks" line (Step 2), and sign and date the CCF.
 - (2) As the MRO, you must note the refusal by checking the "Refusal to Test" box in Step 6 on Copy 2 of the CCF, checking whether the specimen was adulterated or substituted and, if adulterated, nothing the adulterant/reason. If there was another reason for the refusal, check "Other" in Step 6 on Copy 2 of the CCF, and note the reason next to the "Other" box and on the "remarks" lines, as needed. You must then sign and date the CCF.
- (e) As an employee, when you refuse to take a non-DOT test or to sign a non-DOT form, you have not refused to take a DOT test. There are no consequences under DOT agency regulations for refusing to take a non-DOT test.

[65 FR 79526, Dec. 19, 2000, as amended at 66 FR 41953, Aug. 9, 2001; 68 FR 31626, May 28, 2003, June 25, 2008; 75 FR 59108, September 27, 2010]

§ 40.193
What happens when an employee does not provide a sufficient amount of urine for a drug test?

- (a) This section prescribes procedures for situations in which an employee does not provide a sufficient amount of urine to permit a drug test (i.e., 45 mL of urine).
- (b) As the collector, you must do the following:
 - (1) Discard the insufficient specimen, except where the insufficient specimen was out of temperature range or showed evidence of adulteration or tampering (see §40.65(b) and (c)).
 - (2) 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

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- of, the time at which the three-hour period begins and ends.
- (3) If the employee refuses to make the attempt to provide a new urine specimen or leaves the collection site before the collection process is complete, you must discontinue the collection, note the fact on the "Remarks" line of the CCF (Step 2), and immediately notify the DER. This is a refusal to test.
 - (4) If the employee has not provided a sufficient specimen within three hours of the first unsuccessful attempt to provide the specimen, you must discontinue the collection, note the fact on the "Remarks" line of the CCF (Step 2), and immediately notify the DER.
 - (5) Send Copy 2 of the CCF to the MRO and Copy 4 to the DER. You must send or fax these copies to the MRO and DER within 24 hours or the next business day.
- (c) As the DER, when the collector informs you that the employee has not provided a sufficient amount of urine (see paragraph (b)(4) of this section), you must, after consulting with the MRO, direct the employee to obtain, within five days, an evaluation from a licensed physician, acceptable to the MRO, who has expertise in the medical issues raised by the employee's failure to provide a sufficient specimen. (The MRO may perform this evaluation if the MRO has appropriate expertise.)
- (1) As the MRO, if another physician will perform the evaluation, you must provide the other physician with the following information and instructions:
 - (i) That the employee was required to take a DOT drug test, but was unable to provide a sufficient amount of urine to complete the test;
 - (ii) The consequences of the appropriate DOT agency regulation for refusing to take the required drug test;
 - (iii) That the referral physician must agree to follow the requirements of paragraphs (d) through (g) of this section.
 - (2) [Reserved]
 - (d) As the referral physician conducting this evaluation, you must recommend that the MRO make one of the following determinations:
 - (1) A medical condition has, or with a high degree of probability could have, precluded the employee from providing a sufficient amount of urine. As the MRO, if you accept this recommendation, you must:
 - (i) Check "Test Cancelled" (Step 6) on the CCF; and
 - (ii) Sign and date the CCF.
 - (2) There is not an adequate basis for determining that a medical condition has, or with a high degree of probability could have, precluded the employee from providing a sufficient amount of urine. As the MRO, if you accept this recommendation, you must:
 - (i) Check the "Refusal to Test" box and "Other" box in Step 6 on Copy 2 of the CCF and note the reason next to

- the "Other" box and on the "Remarks" lines, as needed.
- (e) For purposes of this paragraph, a medical condition includes an ascertainable physiological condition (e.g., a urinary system dysfunction) or a medically documented pre-existing psychological disorder, but does not include unsupported assertions of "situational anxiety" or dehydration.
 - (f) As the referral physician making the evaluation, after completing your evaluation, you must provide a written statement of your recommendations and the basis for them to the MRO. You must not include in this statement detailed information on the employee's medical condition beyond what is necessary to explain your conclusion.
 - (g) If, as the referral physician making this evaluation in the case of a pre-employment test, you determine that the employee's medical condition is a serious and permanent or long-term disability that is highly likely to prevent the employee from providing a sufficient amount of urine for a very long or indefinite period of time, you must set forth your determination and the reasons for it in your written statement to the MRO. As the MRO, upon receiving such a report, you must follow the requirements of §40.195, where applicable.
 - (h) As the MRO, you must seriously consider and assess the referral physician's recommendations in making your determination about whether the employee has a medical condition that has, or with a high degree of probability could have, precluded the employee from providing a sufficient amount of urine. You must report your determination to the DER in writing as soon as you make it.
 - (i) As the employer, when you receive a report from the MRO indicating that a test is cancelled as provided in paragraph (d)(1) of this section, you take no further action with respect to the employee. The employee remains in the random testing pool.
- [65 FR 79526, Dec. 19, 2000, as amended at 66 FR 41953, Aug. 9, 2001; 75 FR 59108, September 27, 2010]
- § 40.195**
What happens when an individual is unable to provide a sufficient amount of urine for a pre-employment follow-up or return-to-duty test because of a permanent or long-term medical condition?
- (a) This section concerns a situation in which an employee has a medical condition that precludes him or her from providing a sufficient specimen for a pre-employment follow-up or return-to-duty test and the condition involves a permanent or long-term disability. As the MRO in this situation, you must do the following:

- (1) You must determine if there is clinical evidence that the individual is an illicit drug user. You must make this determination by personally conducting, or causing to be conducted, a medical evaluation and through consultation with the employee's physician and/or the physician who conducted the evaluation under §40.193(d).
 - (2) If you do not personally conduct the medical evaluation, you must ensure that one is conducted by a licensed physician acceptable to you.
 - (3) For purposes of this section, the MRO or the physician conducting the evaluation may conduct an alternative test (e.g., blood) as part of the medically appropriate procedures in determining clinical evidence of drug use.
- (b) If the medical evaluation reveals no clinical evidence of drug use, as the MRO, you must report the result to the employer as a negative test with written notations regarding results of both the evaluation conducted under §40.193(d) and any further medical examination. This report must state the basis for the determination that a permanent or long-term medical condition exists, making provision of a sufficient urine specimen impossible, and for the determination that no signs and symptoms of drug use exist.
- (1) Check "Negative" (Step 6) on the CCF.
 - (2) Sign and date the CCF.
- (c) If the medical evaluation reveals clinical evidence of drug use, as the MRO, you must report the result to the employer as a cancelled test with written notations regarding results of both the evaluation conducted under §40.193(d) and any further medical examination. This report must state that a permanent or long-term medical condition exists, making provision of a sufficient urine specimen impossible, and state the reason for the determination that signs and symptoms of drug use exist. Because this is a cancelled test, it does not serve the purposes of a negative test (i.e., the employer is not authorized to allow the employee to begin or resume performing safety-sensitive functions, because a negative test is needed for that purpose).
- (d) For purposes of this section, permanent or long-term medical conditions are those physiological, anatomic, or psychological abnormalities documented as being present prior to the attempted collection, and considered not amenable to correction or cure for an extended period of time, if ever.
- (1) Examples would include destruction (any cause) of the glomerular filtration system leading to renal failure; unrepaired traumatic disruption of the urinary tract; or a severe psychiatric disorder focused on genito-urinary matters.
 - (2) Acute or temporary medical conditions, such as cystitis, urethritis or prostatitis, though they might interfere with collection for a limited period of time, cannot receive the same exceptional consideration as the permanent or long-term conditions discussed in paragraph (d)(1) of this section.

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[65 FR 79526, Dec. 19, 2000, as amended at 66 FR 41953, Aug. 9, 2001]

§ 40.197

What happens when an employer receives a report of a dilute specimen?

- (a) As the employer, if the MRO informs you that a positive drug test was dilute, you simply treat the test as a verified positive test. You must not direct the employee to take another test based on the fact that the specimen was dilute.
- (b) As an employer, if the MRO informs you that a negative test was dilute, take the following action:
 - (1) If the MRO directs you to conduct a recollection under direct observation (i.e., because the creatinine concentration of the specimen was equal to or greater than 2mg/dL, but less than or equal to 5 mg/dL (see §40.155(c)), you must do so immediately.
 - (2) Otherwise (i.e., if the creatinine concentration of the dilute specimen is greater than 5 mg/dL), you may, but are not required to, direct the employee to take another test immediately.
- (i) Such recollections must not be collected under direct observation, unless there is another basis for use of direct observation (see §40.67 (b) and (c)).
- (ii) You must treat all employees the same for this purpose. For example, you must not retest some employees and not others. You may, however, establish different policies for different types of tests (e.g., conduct retests in pre-employment situations, but not in random test situations). You must inform your employees in advance of your decisions on these matters.
- (c) The following provisions apply to all tests you direct an employee to take under paragraph (b) of this section:
 - (1) You must ensure that the employee is given the minimum possible advance notice that he or she must go to the collection site;
 - (2) You must treat the result of the test you directed the employee to take under paragraph (b) of this section—and not a prior test—as the test result of record, on which you rely for purposes of this part;
 - (3) If the result of the test you directed the employee to take under paragraph (b)(1) of this section is also negative and dilute, you are not permitted to make the employee take an additional test because the result was dilute.
 - (4) If the result of the test you directed the employee to take under paragraph (b)(2) of this section is also negative and dilute, you are not permitted to make the employee take an additional test because the result was dilute. Provided, however, that if the MRO directs you to conduct a recollection under direct observation under paragraph (b)(1) of this section, you must immediately do so.
 - (5) If the employee declines to take a test you directed him or her to take under paragraph (b) of this section, the

employee has refused the test for purposes of this part and DOT agency regulations

[68 FR 31626, May 28, 2003; 69 FR 64867, Nov.9, 2004; 73 FR 35974, June 25, 2008]

§ 40.199

What problems always cause a drug test to be cancelled?

- (a) As the MRO, when the laboratory discovers a “fatal flaw” during its processing of incoming specimens (see §40.83), the laboratory will report to you that the specimen has been “Rejected for Testing” (with the reason stated). You must always cancel such a test.
- (b) The following are “fatal flaws”:
 - (1) There is no printed collector's name and no collector's signature;
 - (2) The specimen ID numbers on the specimen bottle and the CCF do not match;
 - (3) The specimen bottle seal is broken or shows evidence of tampering (and a split specimen cannot be redesignated, see §40.83(g)); and
 - (4) Because of leakage or other causes, there is an insufficient amount of urine in the primary specimen bottle for analysis and the specimens cannot be redesignated (see §40.83(g)).
- (c) You must report the result as provided in §40.161.

§ 40.201

What problems always cause a drug test to be cancelled and may result in a requirement for another collection?

- As the MRO, you must cancel a drug test when a laboratory reports that any of the following problems have occurred. You must inform the DER that the test was cancelled. You must also direct the DER to ensure that an additional collection occurs immediately, if required by the applicable procedures specified in paragraphs (a) through (e) of this section.
- (a) The laboratory reports an “Invalid Result.” You must follow applicable procedures in §40.159 (recollection under direct observation may be required).
 - (b) The laboratory reports the result as “Rejected for Testing.” You must follow applicable procedures in §40.161 (a recollection may be required).
 - (c) The laboratory reports that the split specimen failed to reconfirm all of the primary specimen results because the drug(s)/drug metabolite(s) were not detected; adulteration criteria were not met; and/ or substitution criteria were not met. You must follow the applicable procedures in § 40.187(b) – no recollection is required in this case, unless the split specimen creatinine concentration for a substituted primary specimen was greater than or equal to 2mg/dL but less than or equal to 5mg/dL, or the primary specimen had an invalid result which was not reported to the DER. Both these cases require recollection under direct observation
 - (d) The laboratory reports that the split specimen failed to reconfirm all of the primary specimen results, and that the split specimen was invalid. You must follow the

procedures in § 40.187(c)(1) – recollection under direct observation is required in this case.

- (e) The laboratory reports that the split specimen failed to reconfirm all of the primary specimen results because the split specimen was not available for testing or there was no split laboratory available to test the specimen. You must follow the applicable procedures in § 40.187(e) – recollection under direct observation is required in this case.
- (f) The examining physician has determined that there is an acceptable medical explanation of the employee's failure to provide a sufficient amount of urine. You must follow applicable procedures in §40.193(d)(1) (no recollection is required in this case).

[65 FR 79526, Dec. 19, 2000, as amended at 73 FR 35974, June 25, 2008]

§ 40.203

What problems cause a drug test to be cancelled unless they are corrected?

- (a) As the MRO, when a laboratory discovers a “correctable flaw” during its processing of incoming specimens (see §40.83), the laboratory will attempt to correct it. If the laboratory is unsuccessful in this attempt, it will report to you that the specimen has been “Rejected for Testing” (with the reason stated).
- (b) The following is a “correctable flaw” that laboratories must attempt to correct: The collector's signature is omitted on the certification statement on the CCF.
- (c) As the MRO, when you discover a “correctable flaw” during your review of the CCF, you must cancel the test unless the flaw is corrected.
- (d) The following are correctable flaws that you must attempt to correct:
 - (1) The employee's signature is omitted from the certification statement, unless the employee's failure or refusal to sign is noted on the “Remarks” line of the CCF.
 - (2) The certifying scientist's signature is omitted on Copy 1 of the CCF for a positive, adulterated, substituted, or invalid test result.
 - (3) The collector uses a non-Federal form or an expired CCF for the test. This flaw may be corrected through the procedure set forth in §40.205(b)(2), provided that the collection testing process has been conducted in accordance with the procedures of this part in an HHS-certified laboratory. During the period October 1, 2010-November 30, 2011, you are not required to cancel a test because of the use of an old CCF. Beginning December 1, 2011, if the problem is not corrected, you must cancel the test.

[65 FR 79526, Dec. 19, 2000, as amended at 66 FR 41954, Aug. 9, 2001; 75 FR 59108, September 27, 2010; 76 FR 59578, Sep 27, 2011]

§ 40.205

How are drug test problems corrected?

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- (a) As a collector, you have the responsibility of trying to successfully complete a collection procedure for each employee.
- (1) If, during or shortly after the collection process, you become aware of any event that prevents the completion of a valid test or collection (e.g., a procedural or paperwork error), you must try to correct the problem promptly, if doing so is practicable. You may conduct another collection as part of this effort.
- (2) If another collection is necessary, you must begin the new collection procedure as soon as possible, using a new CCF and a new collection kit.
- (b) If, as a collector, laboratory, MRO, employer, or other person implementing these drug testing regulations, you become aware of a problem that can be corrected (see §40.203), but which has not already been corrected under paragraph (a) of this section, you must take all practicable action to correct the problem so that the test is not cancelled.
- (1) If the problem resulted from the omission of required information, you must, as the person responsible for providing that information, supply in writing the missing information and a statement that it is true and accurate. For example, suppose you are a collector, and you forgot to make a notation on the "Remarks" line of the CCF that the employee did not sign the certification. You would, when the problem is called to your attention, supply a signed statement that the employee failed or refused to sign the certification and that your statement is true and accurate. You must supply this information on the same business day on which you are notified of the problem, transmitting it by fax or courier.
- (2) If the problem is the use of a non-Federal form or an expired Federal form, you must provide a signed statement (i.e., a memorandum for the record). It must state that the incorrect form contains all the information needed for a valid DOT drug test, and that the incorrect form was used inadvertently or as the only means of conducting a test, in circumstances beyond your control. The statement must also list the steps you have taken to prevent future use of non-Federal forms or expired Federal forms for DOT tests. For this flaw to be corrected, the test of the specimen must have occurred at a HHS-certified laboratory where it was tested consistent with the requirements of this part. You must supply this information on the same business day on which you are notified of the problem, transmitting it by fax or courier.
- (3) You must maintain the written documentation of a correction with the CCF.
- (4) You must mark the CCF in such a way (e.g., stamp noting correction) as to make it obvious on the face of the CCF that you corrected the flaw.
- (c) If the correction does not take place, as the MRO you must cancel the test.

[65 FR 79526, Dec. 19, 2000, as amended at 66 FR 41954, Aug. 9, 2001]

§ 40.207

What is the effect of a cancelled drug test?

- (a) A cancelled drug test is neither positive nor negative.
- (1) As an employer, you must not attach to a cancelled test the consequences of a positive test or other violation of a DOT drug testing regulation (e.g., removal from a safety-sensitive position).
- (2) As an employer, you must not use a cancelled test for the purposes of a negative test to authorize the employee to perform safety-sensitive functions (i.e., in the case of a pre-employment, return-to-duty, or follow-up test).
- (3) However, as an employer, you must not direct a recollection for an employee because a test has been cancelled, except in the situations cited in paragraph (a)(2) of this section or other provisions of this part that require another test to be conducted (e.g., §§40.159(a)(5) and 40.187(b)(2), (c)(1), and (e)).
- (b) A cancelled test does not count toward compliance with DOT requirements (e.g., being applied toward the number of tests needed to meet the employer's minimum random testing rate).
- (c) A cancelled DOT test does not provide a valid basis for an employer to conduct a non-DOT test (i.e., a test under company authority).

[65 FR 79526, Dec. 19, 2000, as amended at 73 FR 35975, June 25, 2008]

§ 40.208

What problem requires corrective action but does not result in the cancellation of a test?

- (a) If, as a laboratory, collector, employer, or other person implementing the DOT drug testing program, you become aware that the specimen temperature on the CCF was not checked and the "Remarks" line did not contain an entry regarding the temperature being out of range, you must take corrective action, including securing a memorandum for the record explaining the problem and taking appropriate action to ensure that the problem does not recur.
- (b) This error does not result in the cancellation of the test.
- (c) As an employer or service agent, this error, even though not sufficient to cancel a drug test result, may subject you to enforcement action under DOT agency regulations or Subpart R of this part.

[66 FR 41954, Aug. 9, 2001]

§ 40.209

What procedural problems do not result in the cancellation of a test and do not require corrective action?

- (a) As a collector, laboratory, MRO, employer or other person administering the drug testing process, you must document any errors in the testing process of which you become aware, even if they are not considered problems that will cause a test to be cancelled as listed in this subpart.

Decisions about the ultimate impact of these errors will be determined by other administrative or legal proceedings, subject to the limitations of paragraph (b) of this section.

- (b) No person concerned with the testing process may declare a test cancelled based on an error that does not have a significant adverse effect on the right of the employee to have a fair and accurate test. Matters that do not result in the cancellation of a test include, but are not limited to, the following:
- (1) A minor administrative mistake (e.g., the omission of the employee's middle initial, a transposition of numbers in the employee's social security number, the omission of the DOT Agency in Step 1-D of the CCF);
- (2) An error that does not affect employee protections under this part (e.g., the collector's failure to add bluing agent to the toilet bowl, which adversely affects only the ability of the collector to detect tampering with the specimen by the employee);
- (3) The collection of a specimen by a collector who is required to have been trained (see §40.33), but who has not met this requirement;
- (4) A delay in the collection process (see §40.61(a));
- (5) Verification of a test result by an MRO who has the basic credentials to be qualified as an MRO (see §40.121(a) through (b)) but who has not met training and/or documentation requirements (see §40.121(c) through (e));
- (6) The failure to directly observe or monitor a collection that the rule requires or permits to be directly observed or monitored, or the unauthorized use of direct observation or monitoring for a collection;
- (7) The fact that a test was conducted in a facility that does not meet the requirements of §40.41;
- (8) If the specific name of the courier on the CCF is omitted or erroneous;
- (9) Personal identifying information is inadvertently contained on the CCF (e.g., the employee signs his or her name on Copy 1); or
- (10) Claims that the employee was improperly selected for testing.
- (c) As an employer or service agent, these types of errors, even though not sufficient to cancel a drug test result, may subject you to enforcement action under DOT agency regulations or action under Subpart R of this part.

[65 FR 79526, Dec. 19, 2000, as amended at 66 FR 41954, Aug. 9, 2001; 75 FR 59108, September 27, 2010]

Subpart J - Alcohol Testing Personnel

§ 40.211

Who conducts DOT alcohol tests?

- (a) Screening test technicians (STTs) and breath alcohol technicians (BATs) meeting their respective requirements of this subpart

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are the only people authorized to conduct DOT alcohol tests.

- (b) An STT can conduct only alcohol screening tests, but a BAT can conduct alcohol screening and confirmation tests.
- (c) As a BAT- or STT-qualified immediate supervisor of a particular employee, you may not act as the STT or BAT when that employee is tested, unless no other STT or BAT is available and DOT agency regulations do not prohibit you from doing so.

§ 40.213

What training requirements must STTs and BATs meet?

To be permitted to act as a BAT or STT in the DOT alcohol testing program, you must meet each of the requirements of this section:

- (a) **Basic information.** You must be knowledgeable about the alcohol testing procedures in this part and the current DOT guidance. These documents and information are available from ODAPC (Department of Transportation, 400 7th Street, SW., Room 10403, Washington DC, 20590, 202-366-3784, or on the ODAPC web site, <http://www.dot.gov/ost/dapc>).
- (b) **Qualification training.** You must receive qualification training meeting the requirements of this paragraph (b).
 - (1) Qualification training must be in accordance with the DOT Model BAT or STT Course, as applicable. The DOT Model Courses are available from ODAPC (Department of Transportation, 400 7th Street, SW., Room 10403, Washington DC, 20590, 202-366-3784, or on the ODAPC web site, <http://www.dot.gov/ost/dapc>). The training can also be provided using a course of instruction equivalent to the DOT Model Courses. On request, ODAPC will review BAT and STT instruction courses for equivalency.
 - (2) Qualification training must include training to proficiency in using the alcohol testing procedures of this part and in the operation of the particular alcohol testing device(s) (i.e., the ASD(s) or EBT(s)) you will be using.
 - (3) The training must emphasize that you are responsible for maintaining the integrity of the testing process, ensuring the privacy of employees being tested, and avoiding conduct or statements that could be viewed as offensive or inappropriate.
 - (4) The instructor must be an individual who has demonstrated necessary knowledge, skills, and abilities by regularly conducting DOT alcohol tests as an STT or BAT, as applicable, for a period of at least a year, who has conducted STT or BAT training, as applicable, under this part for a year, or who has successfully completed a "train the trainer" course.
- (c) **Initial Proficiency Demonstration.** Following your completion of qualification training under paragraph (b) of this section, you must demonstrate proficiency in alcohol testing under this part by completing seven consecutive error-free mock tests (BATs) or five consecutive error-free tests (STTs).

- (1) Another person must monitor and evaluate your performance, in person or by a means that provides real-time observation and interaction between the instructor and trainee, and attest in writing that the mock collections are "error-free." This person must be an individual who meets the requirements of paragraph (b)(4) of this section.
- (2) These tests must use the alcohol testing devices (e.g., EBT(s) or ASD(s)) that you will use as a BAT or STT.
- (3) If you are an STT who will be using an ASD that indicates readings by changes, contrasts, or other readings in color, you must demonstrate as part of the mock test that you are able to discern changes, contrasts, or readings correctly.
- (d) **Schedule for qualification training and initial proficiency demonstration.** The following is the schedule for qualification training and the initial proficiency demonstration you must meet:
 - (1) If you became a BAT or STT before August 1, 2001, you were required to have met the requirements set forth in paragraphs (b) and (c) of this section, and you do not have to meet them again.
 - (2) If you become a BAT or STT on or after August 1, 2001, you must meet the requirements of paragraphs (b) and (c) of this section before you begin to perform BAT or STT functions.
- (e) **Refresher training.** No less frequently than every five years from the date on which you satisfactorily complete the requirements of paragraphs (b) and (c) of this section, you must complete refresher training that meets all the requirements of paragraphs (b) and (c) of this section. If you are a BAT or STT who completed qualification training before January 1, 1998, you are not required to complete refresher training until January 1, 2003.
- (f) **Error Correction Training.** If you make a mistake in the alcohol testing process that causes a test to be cancelled (i.e., a fatal or uncorrected flaw), you must undergo error correction training. This training must occur within 30 days of the date you are notified of the error that led to the need for retraining.
 - (1) Error correction training must be provided and your proficiency documented in writing by a person who meets the requirements of paragraph (b)(4) of this section.
 - (2) Error correction training is required to cover only the subject matter area(s) in which the error that caused the test to be cancelled occurred.
 - (3) As part of the error correction training, you must demonstrate your proficiency in the alcohol testing procedures of this part by completing three consecutive error-free mock tests. The mock tests must include one uneventful scenario and two scenarios related to the area(s) in which your error(s) occurred. The person providing the training must monitor and evaluate your performance and attest in writing that the mock tests were error-free.

- (g) **Documentation.** You must maintain documentation showing that you currently meet all requirements of this section. You must provide this documentation on request to DOT agency representatives and to employers and C/TPAs who are negotiating to use your services.

- (h) **Other persons who may serve as BATs or STTs.**

- (1) Anyone meeting the requirements of this section to be a BAT may act as an STT, provided that the individual has demonstrated initial proficiency in the operation of the ASD that he or she is using, as provided in paragraph (c) of this section.
- (2) Law enforcement officers who have been certified by state or local governments to conduct breath alcohol testing are deemed to be qualified as BATs. They are not required to also complete the training requirements of this section in order to act as BATs. In order for a test conducted by such an officer to be accepted under DOT alcohol testing requirements, the officer must have been certified by a state or local government to use the EBT or ASD that was used for the test.

[65 FR 79526, Dec. 19, 2000, as amended at 66 FR 41954, Aug. 9, 2001]

§ 40.215

What information about the DER do employers have to provide to BATs and STTs?

As an employer, you must provide to the STTs and BATs the name and telephone number of the appropriate DER (and C/TPA, where applicable) to contact about any problems or issues that may arise during the testing process.

Subpart K - Testing Sites, Forms, Equipment and Supplies Used in Alcohol Testing

Subpart L—Alcohol Screening Tests

§ 40.243

What is the procedure for an alcohol screening test using an EBT or non-evidential breath ASD?

As the BAT or STT, you must take the following steps:

- (a) Select, or allow the employee to select, an individually wrapped or sealed mouthpiece from the testing materials.
- (b) Open the individually wrapped or sealed mouthpiece in view of the employee and insert it into the device in accordance with the manufacturer's instructions.
- (c) Instruct the employee to blow steadily and forcefully into the mouthpiece for at least six seconds or until the device indicates that an adequate amount of breath has been obtained.
- (d) Show the employee the displayed test result.
- (e) If the device is one that prints the test number, testing device name and serial number, time, and result directly onto the ATF, you must check to ensure that the

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information has been printed correctly onto the ATF.

- (f) If the device is one that prints the test number, testing device name and serial number, time and result, but on a separate printout rather than directly onto the ATF, you must affix the printout of the information to the designated space on the ATF with tamper-evident tape or use a self-adhesive label that is tamper-evident.
- (g) If the device is one that does not print the test number, testing device name and serial number, time, and result, or it is a device not being used with a printer, you must record this information in Step 3 of the ATF.

§ 40.245

What is the procedure for an alcohol screening test using a saliva ASD or a breath tube ASD?

(a) As the STT or BAT, you must take the following steps when using the saliva ASD:

- (1) Check the expiration date on the device or on the package containing the device and show it to the employee. You may not use the device after its expiration date.
- (2) Open an individually wrapped or sealed package containing the device in the presence of the employee.
- (3) Offer the employee the opportunity to use the device. If the employee uses it, you must instruct the employee to insert it into his or her mouth and use it in a manner described by the device's manufacturer.
- (4) If the employee chooses not to use the device, or in all cases in which a new test is necessary because the device did not activate (see paragraph (a)(7) of this section), you must insert the device into the employee's mouth and gather saliva in the manner described by the device's manufacturer. You must wear single-use examination or similar gloves while doing so and change them following each test.
- (5) When the device is removed from the employee's mouth, you must follow the manufacturer's instructions regarding necessary next steps in ensuring that the device has activated.
- (6) (i) If you were unable to successfully follow the procedures of paragraphs (a)(3) through (a)(5) of this section (e.g., the device breaks, you drop the device on the floor), you must discard the device and conduct a new test using a new device.
 - (ii) The new device you use must be one that has been under your control or that of the employee before the test.
 - (iii) You must note on the "Remarks" line of the ATF the reason for the new test. (Note: You may continue using the same ATF with which you began the test.)
 - (iv) You must offer the employee the choice of using the device or having you use it unless the employee, in the opinion of the STT or BAT, was responsible (e.g., the employee dropped the device) for the new test needing to be conducted.

- (v) If you are unable to successfully follow the procedures of paragraphs (a)(3) through (a)(5) of this section on the new test, you must end the collection and put an explanation on the "Remarks" line of the ATF.
 - (vi) You must then direct the employee to take a new test immediately, using an EBT for the screening test.
- (7) If you are able to successfully follow the procedures of paragraphs (a)(3)—(a)(5) of this section, but the device does not activate, you must discard the device and conduct a new test, in the same manner as provided in paragraph (a)(6) of this section. In this case, you must place the device into the employee's mouth to collect saliva for the new test.
 - (8) You must read the result displayed on the device no sooner than the device's manufacturer instructs. In all cases the result displayed must be read within 15 minutes of the test. You must then show the device and its reading to the employee and enter the result on the ATF.
 - (9) You must never re-use devices, swabs, gloves or other materials used in saliva testing.
 - (10) You must note the fact that you used a saliva ASD in Step 3 of the ATF.
- (b) As the STT or BAT, you must take the following steps when using the breath tube ASD:
- (1) Check the expiration date on the device or on the detector device and the package containing the device and show it to the employee. You must not use the device or the analyzer after their expiration date. You must not use an analyzer which is not specifically pre-calibrated for the device being used in the collection.
 - (2) Remove a device from the package and secure an inflation bag onto the appropriate end of the device, as directed by the manufacturer on the device's instructions.
 - (3) Break the tube's ampule in the presence of the employee.
 - (4) Offer the employee the opportunity to use the device. If the employee chooses to use (e.g. hold) the device, instruct the employee to blow forcefully and steadily into the blowing end of device until the inflation bag fills with air (approximately 12 seconds).
 - (5) If the employee chooses not to hold the device, you must hold it and provide the use instructions in paragraph (b)(4) of this section.
 - (6) When the employee completes the breath process, take the device from the employee (or if you were holding it, remove it from the employee's mouth), remove the inflation bag, and prepare the device to be read by the analyzer in accordance with the manufacturer's directions.
 - (7) (i) If you were unable to successfully follow the procedures of paragraphs (b)(4) through (b)(6) of this section (e.g., the device breaks apart, the employee did not fill the inflation

- bag), you must discard the device and conduct a new test using a new one.
 - (ii) The new device you use must be one that has been under your control or that of the employer before the test.
 - (iii) You must note on the "Remarks" line of the ATF the reason for the new test. (Note: You may continue using the same ATF with which you began the test.)
 - (iv) You must offer the employee the choice of holding the device or having you hold it unless the employee, in the your opinion, was responsible (e.g., the employee failed to fill the inflation bag) for the new test needing to be conducted.
 - (v) If you are unable to successfully follow the procedures of paragraphs (b)(4) through (b)(6) of this section on the new test, you must end the collection and put an explanation on the "Remarks" line of the ATF.
 - (vi) You must then direct the employee to take a new test immediately, using another type of ASD (e.g., saliva device) or an EBT.
- (8) If you were able to successfully follow the procedures of paragraphs (b)(4) through (b)(6) of this section and after having waited the required amount of time directed by the manufacturer for the detector device to incubate, you must place the device in the analyzer in accordance with the manufacturer's directions. The result must be read from the analyzer no earlier than the required incubation time of the device. In all cases, the result must be read within 15 minutes of the test.
 - (9) You must follow the manufacturer's instructions for determining the result of the test. You must show the analyzer result to the employee and record the result on Step 3 of the ATF.
 - (10) You must never re-use detector devices or any gloves used in breath tube testing. The inflation bag must be voided of air following removal from a device. Inflation bags and electronic analyzers may be re-used but only in accordance with the manufacturer's directions.
 - (11) You must note the fact that you used a breath tube device in Step 3 of the ATF.
- [67 FR 61522, Oct. 1, 2002, as amended at 72 FR 1299, Jan. 11, 2007; 75 FR 8526, February 25, 2010]

Subpart M - Alcohol Confirmation Tests

Subpart N - Problems in Alcohol Testing

§ 40.261

What is a refusal to take an alcohol test, and what are the consequences?

- (a) As an employee, you are considered to have refused to take an alcohol test if you:
 - (1) Fail to appear for any test (except a pre-employment test) within a reasonable time, as determined by the employer,

consistent with applicable DOT agency regulations, after being directed to do so by the employer. This includes the failure of an employee (including an owner-operator) to appear for a test when called by a C/TPA (see §40.241(a));

(2) Fail to remain at the testing site until the testing process is complete; Provided, That an employee who leaves the testing site before the testing process commences (see §40.243(a)) for a pre-employment test is not deemed to have refused to test;

(3) Fail to provide an adequate amount of saliva or breath for any alcohol test required by this part or DOT agency regulations; Provided, That an employee who does not provide an adequate amount of breath or saliva because he or she has left the testing site before the testing process commences (see §40.243(a)) for a pre-employment test is not deemed to have refused to test;

(4) Fail to provide a sufficient breath specimen, and the physician has determined, through a required medical evaluation, that there was no adequate medical explanation for the failure (see §40.265(c));

(5) Fail to undergo a medical examination or evaluation, as directed by the employer as part of the insufficient breath procedures outlined at §40.265(c);

(6) Fail to sign the certification at Step 2 of the ATF (see §§40.241(g) and 40.251(d)); or

(7) Fail to cooperate with any part of the testing process.

(b) As an employee, if you refuse to take an alcohol test, you incur the same consequences specified under DOT agency regulations for a violation of those DOT agency regulations.

(c) As a BAT or an STT, or as the physician evaluating a “shy lung” situation, when an employee refuses to test as provided in paragraph (a) of this section, you must terminate the portion of the testing process in which you are involved, document the refusal on the ATF (or in a separate document which you cause to be attached to the form), immediately notify the DER by any means (e.g., telephone or secure fax machine) that ensures the refusal notification is immediately received. You must make this notification directly to the DER (not using a C/TPA as an intermediary).

(d) As an employee, when you refuse to take a non-DOT test or to sign a non-DOT form, you have not refused to take a DOT test. There are no consequences under DOT agency regulations for such a refusal.

[65 FR 79526, Dec. 19, 2000, as amended at 66 FR 41954, Aug. 9, 2001]

§ 40.263
What happens when an employee is unable to provide a sufficient amount of saliva for an alcohol screening test?

- (a) As the STT, you must take the following steps if an employee is unable to provide

sufficient saliva to complete a test on a saliva screening device (e.g., the employee does not provide sufficient saliva to activate the device).

(1) You must conduct a new screening test using a new screening device.

(2) If the employee refuses to make the attempt to complete the new test, you must discontinue testing, note the fact on the “Remarks” line of the ATF, and immediately notify the DER. This is a refusal to test.

(3) If the employee has not provided a sufficient amount of saliva to complete the new test, you must note the fact on the “Remarks” line of the ATF and immediately notify the DER.

(b) As the DER, when the STT informs you that the employee has not provided a sufficient amount of saliva (see paragraph (a)(3) of this section), you must immediately arrange to administer an alcohol test to the employee using an EBT or other breath testing device.

§ 40.265
What happens when an employee is unable to provide a sufficient amount of breath for an alcohol test?

- (a) If an employee does not provide a sufficient amount of breath to permit a valid breath test, you must take the steps listed in this section.
- (b) As the BAT or STT, you must instruct the employee to attempt again to provide a sufficient amount of breath and about the proper way to do so.
- (1) If the employee refuses to make the attempt, you must discontinue the test, note the fact on the “Remarks” line of the ATF, and immediately notify the DER. This is a refusal to test.
- (2) If the employee again attempts and fails to provide a sufficient amount of breath, you may provide another opportunity to the employee to do so if you believe that there is a strong likelihood that it could result in providing a sufficient amount of breath.
- (3) When the employee's attempts under paragraph (b)(2) of this section have failed to produce a sufficient amount of breath, you must note the fact on the “Remarks” line of the ATF and immediately notify the DER.
- (4) If you are using an EBT that has the capability of operating manually, you may attempt to conduct the test in manual mode.
- (5) If you are qualified to use a saliva ASD and you are in the screening test stage, you may change to a saliva ASD only to complete the screening test.
- (c) As the employer, when the BAT or STT informs you that the employee has not provided a sufficient amount of breath, you must direct the employee to obtain, within five days, an evaluation from a licensed physician who is acceptable to you and who has expertise in the medical issues raised by the employee's failure to provide a sufficient specimen.
- (1) You are required to provide the physician who will conduct the

evaluation with the following information and instructions:

(i) That the employee was required to take a DOT breath alcohol test, but was unable to provide a sufficient amount of breath to complete the test;

(ii) The consequences of the appropriate DOT agency regulation for refusing to take the required alcohol test;

(iii) That the physician must provide you with a signed statement of his or her conclusions; and

(iv) That the physician, in his or her reasonable medical judgment, must base those conclusions on one of the following determinations:

(A) A medical condition has, or with a high degree of probability could have, precluded the employee from providing a sufficient amount of breath. The physician must not include in the signed statement detailed information on the employee's medical condition. In this case, the test is cancelled.

(B) There is not an adequate basis for determining that a medical condition has, or with a high degree of probability could have, precluded the employee from providing a sufficient amount of breath. This constitutes a refusal to test.

(C) For purposes of paragraphs (c)(1)(iv)(A) and (B) of this section, a medical condition includes an ascertainable physiological condition (e.g., a respiratory system dysfunction) or a medically documented pre-existing psychological disorder, but does not include unsupported assertions of “situational anxiety” or hyperventilation.

(2) As the physician making the evaluation, after making your determination, you must provide a written statement of your conclusions and the basis for them to the DER directly (and not through a C/TPA acting as an intermediary). You must not include in this statement detailed information on the employee's medical condition beyond what is necessary to explain your conclusion.

(3) Upon receipt of the report from the examining physician, as the DER you must immediately inform the employee and take appropriate action based upon your DOT agency regulations.

§ 40.267
What problems always cause an alcohol test to be cancelled?

As an employer, a BAT, or an STT, you must cancel an alcohol test if any of the following problems occur. These are “fatal flaws.” You must inform the DER that the test was cancelled and must be treated as if the test never occurred. These problems are:

(a) In the case of a screening test conducted on a saliva ASD or a breath tube ASD:

(1) The STT or BAT reads the result either sooner than or later than the time allotted by the manufacturer and this Part (see

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- §40.245(a)(8) for the saliva ASD and §40.245(b)(8) for the breath tube ASD).
- (2) The saliva ASD does not activate (see §40.245(a)(7)); or
 - (3) The device is used for a test after the expiration date printed on the device or on its package (see §40.245(a)(1) for the saliva ASD and §40.245(b)(1) for the breath tube ASD).
 - (4) The breath tube ASD is tested with an analyzer which has not been pre-calibrated for that device's specific lot (see §40.245(b)(1)).
- (b) In the case of a screening or confirmation test conducted on an EBT, the sequential test number or alcohol concentration displayed on the EBT is not the same as the sequential test number or alcohol concentration on the printed result (see §40.253(c), (e) and (f)).
- (c) In the case of a confirmation test:
- (1) The BAT conducts the confirmation test before the end of the minimum 15-minute waiting period (see §40.251(a)(1));
 - (2) The BAT does not conduct an air blank before the confirmation test (see §40.253(a));
 - (3) There is not a 0.00 result on the air blank conducted before the confirmation test (see §40.253(a)(1) and (2));
 - (4) The EBT does not print the result (see §40.253(f)); or
 - (5) The next external calibration check of the EBT produces a result that differs by more than the tolerance stated in the QAP from the known value of the test standard. In this case, every result of 0.02 or above obtained on the EBT since the last valid external calibration check is cancelled (see §40.233(a)(1) and (c)(3)).

[65 FR 79526, Dec. 19, 2000, as amended at 67 FR 61522, Oct. 1, 2002, February 25, 2010]

§ 40.269

What problems cause an alcohol test to be cancelled unless they are corrected?

As a BAT or STT, or employer, you must cancel an alcohol test if any of the following problems occur, unless they are corrected. These are "correctable flaws." These problems are:

- (a) The BAT or STT does not sign the ATF (see §§40.247(a)(1) and 40.255(a)(1)).
- (b) The BAT or STT fails to note on the "Remarks" line of the ATF that the employee has not signed the ATF after the result is obtained (see §40.255(a)(2)).
- (c) The BAT or STT uses a non-DOT form for the test (see §40.225(a)).

§ 40.271

How are alcohol testing problems corrected?

- (a) As a BAT or STT, you have the responsibility of trying to complete successfully an alcohol test for each employee.
- (1) If, during or shortly after the testing process, you become aware of any event that will cause the test to be cancelled (see §40.267), you must try to correct the problem promptly, if practicable.

- You may repeat the testing process as part of this effort.
- (2) If repeating the testing process is necessary, you must begin a new test as soon as possible. You must use a new ATF, a new sequential test number, and, if needed, a new ASD and/or a new EBT. It is permissible to use additional technical capabilities of the EBT (e.g., manual operation if you have been trained to do so in accordance with §40.213(c).
 - (3) If repeating the testing process is necessary, you are not limited in the number of attempts to complete the test, provided that the employee is making a good faith effort to comply with the testing process.
 - (4) If another testing device is not available for the new test at the testing site, you must immediately notify the DER and advise the DER that the test could not be completed. As the DER who receives this information, you must make all reasonable efforts to ensure that the test is conducted at another testing site as soon as possible.
- (b) If, as an STT, BAT, employer or other service agent administering the testing process, you become aware of a "correctable flaw" (see §40.269) that has not already been corrected, you must take all practicable action to correct the problem so that the test is not cancelled.
- (1) If the problem resulted from the omission of required information, you must, as the person responsible for providing that information, supply in writing the missing information and a signed statement that it is true and accurate. For example, suppose you are a BAT and you forgot to make a notation on the "Remarks" line of the ATF that the employee did not sign the certification. You would, when the problem is called to your attention, supply a signed statement that the employee failed or refused to sign the certification after the result was obtained, and that your signed statement is true and accurate.
 - (2) If the problem is the use of a non-DOT form, you must, as the person responsible for the use of the incorrect form, certify in writing that the incorrect form contains all the information needed for a valid DOT alcohol test. You must also provide a signed statement that the incorrect form was used inadvertently or as the only means of conducting a test, in circumstances beyond your control, and the steps you have taken to prevent future use of non-DOT forms for DOT tests. You must supply this information on the same business day on which you are notified of the problem, transmitting it by fax or courier.
 - (c) If you cannot correct the problem, you must cancel the test.

§ 40.273

What is the effect of a cancelled alcohol test?

- (a) A cancelled alcohol test is neither positive nor negative.

- (1) As an employer, you must not attach to a cancelled test the consequences of a test result that is 0.02 or greater (e.g., removal from a safety-sensitive position).
 - (2) As an employer, you must not use a cancelled test in a situation where an employee needs a test result that is below 0.02 (e.g., in the case of a return-to-duty or follow-up test to authorize the employee to perform safety-sensitive functions).
 - (3) As an employer, you must not direct a recollection for an employee because a test has been cancelled, except in the situations cited in paragraph (a)(2) of this section or other provisions of this part.
- (b) A cancelled test does not count toward compliance with DOT requirements, such as a minimum random testing rate.
- (c) When a test must be cancelled, if you are the BAT, STT, or other person who determines that the cancellation is necessary, you must inform the affected DER within 48 hours of the cancellation.
- (d) A cancelled DOT test does not provide a valid basis for an employer to conduct a non-DOT test (i.e., a test under company authority).

§ 40.275

What is the effect of procedural problems that are not sufficient to cancel an alcohol test?

- (a) As an STT, BAT, employer, or a service agent administering the testing process, you must document any errors in the testing process of which you become aware, even if they are not "fatal flaws" or "correctable flaws" listed in this subpart. Decisions about the ultimate impact of these errors will be determined by administrative or legal proceedings, subject to the limitation of paragraph (b) of this section.
- (b) No person concerned with the testing process may declare a test cancelled based on a mistake in the process that does not have a significant adverse effect on the right of the employee to a fair and accurate test. For example, it is inconsistent with this part to cancel a test based on a minor administrative mistake (e.g., the omission of the employee's middle initial) or an error that does not affect employee protections under this part. Nor does the failure of an employee to sign in Step 4 of the ATF result in the cancellation of the test. Nor is a test to be cancelled on the basis of a claim by an employee that he or she was improperly selected for testing.
- (c) As an employer, these errors, even though not sufficient to cancel an alcohol test result, may subject you to enforcement action under DOT agency regulations.

§ 40.277

Are alcohol tests other than saliva or breath permitted under these regulations?

No, other types of alcohol tests (e.g., blood and urine) are not authorized for testing done under this part. Only saliva or breath for screening tests and breath for confirmation tests using approved devices are permitted.

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Subpart O - Substance Abuse Professionals and the Return-to-Duty Process

§ 40.281

Who is qualified to act as a SAP?

To be permitted to act as a SAP in the DOT drug testing program, you must meet each of the requirements of this section:

- (a) **Credentials.** You must have one of the following credentials:
 - (1) You are a licensed physician (Doctor of Medicine or Osteopathy);
 - (2) You are a licensed or certified social worker;
 - (3) You are a licensed or certified psychologist;
 - (4) You are a licensed or certified employee assistance professional;
 - (5) You are a state-licensed or certified marriage and family therapist; or
 - (6) You are a drug and alcohol counselor certified by the National Association of Alcoholism and Drug Abuse Counselors Certification Commission (NAADAC); or by the International Certification Reciprocity Consortium/Alcohol and Other Drug Abuse (ICRC); or by the National Board for Certified Counselors, Inc. and Affiliates/Master Addictions Counselor (NBCC).
- (b) **Basic knowledge.** You must be knowledgeable in the following areas:
 - (1) You must be knowledgeable about and have clinical experience in the diagnosis and treatment of alcohol and controlled substances-related disorders.
 - (2) You must be knowledgeable about the SAP function as it relates to employer interests in safety-sensitive duties.
 - (3) 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, and you keep current on any changes to these materials. These documents are available from ODAPC (Department of Transportation, 400 7th Street, SW., Room 10403, Washington DC, 20590 (202-366-3784), or on the ODAPC web site (<http://www.dot.gov/ost/dapc>).
- (c) **Qualification training.** You must receive qualification training meeting the requirements of this paragraph (c).
 - (1) Qualification training must provide instruction on the following subjects:
 - (i) Background, rationale, and coverage of the Department's drug and alcohol testing program;
 - (ii) 49 CFR Part 40 and DOT agency drug and alcohol testing rules;
 - (iii) Key DOT drug testing requirements, including collections, laboratory testing, MRO review, and problems in drug testing;
 - (iv) Key DOT alcohol testing requirements, including the testing process, the role of BATs and STTs, and problems in alcohol tests;
 - (v) SAP qualifications and prohibitions;
 - (vi) The role of the SAP in the return-to-duty process, including the initial employee evaluation, referrals for

- (vii) education and/or treatment, the follow-up evaluation, continuing treatment recommendations, and the follow-up testing plan;
 - (viii) SAP consultation and communication with employers, MROs, and treatment providers;
 - (ix) Reporting and recordkeeping requirements;
 - (x) Issues that SAPs confront in carrying out their duties under the program.
- (2) Following your completion of qualification training under paragraph (c)(1) of this section, you must satisfactorily complete an examination administered by a nationally-recognized professional or training organization. The examination must comprehensively cover all the elements of qualification training listed in paragraph (c)(1) of this section.
 - (3) The following is the schedule for qualification training you must meet:
 - (i) If you became a SAP before August 1, 2001, you must meet the qualification training requirement no later than December 31, 2003.
 - (ii) If you become a SAP between August 1, 2001, and December 31, 2003, you must meet the qualification training requirement no later than December 31, 2003.
 - (iii) If you become a SAP on or after January 1, 2004, you must meet the qualification training requirement before you begin to perform SAP functions.
 - (d) **Continuing education.** During each three-year period from the date on which you satisfactorily complete the examination under paragraph (c)(2) of this section, you must complete continuing education consisting of at least 12 professional development hours (e.g., CEUs) relevant to performing SAP functions.
 - (1) This continuing education must include material concerning new technologies, interpretations, recent guidance, rule changes, and other information about developments in SAP practice, pertaining to the DOT program, since the time you met the qualification training requirements of this section.
 - (2) Your continuing education activities must include documentable assessment tools to assist you in determining whether you have adequately learned the material.
 - (e) **Documentation.** You must maintain documentation showing that you currently meet all requirements of this section. You must provide this documentation on request to DOT agency representatives and to employers and C/TPAs who are using or contemplating using your services.
- [65 FR 79526, Dec. 19, 2000, as amended at 69 FR 3022, Jan. 22, 2004]
- ### § 40.283
- #### How does a certification organization obtain recognition for its members as SAPs?
- (a) If you represent a certification organization that wants DOT to authorize its certified drug and alcohol counselors to be added to

- (b) §40.281(a)(6), you may submit a written petition to DOT requesting a review of your petition for inclusion.
- (b) You must obtain the National Commission for Certifying Agencies (NCCA) accreditation before DOT will act on your petition.
- (c) You must also meet the minimum requirements of Appendix E to this part before DOT will act on your petition.

§ 40.285

When is a SAP evaluation required?

- (a) As an employee, when you have violated DOT drug and alcohol regulations, you cannot again perform any DOT safety-sensitive duties for any employer until and unless you complete the SAP evaluation, referral, and education/treatment process set forth in this subpart and in applicable DOT agency regulations. The first step in this process is a SAP evaluation.
- (b) For purposes of this subpart, a verified positive DOT drug test result, a DOT alcohol test with a result indicating an alcohol concentration of 0.04 or greater, a refusal to test (including by adulterating or substituting a urine specimen) or any other violation of the prohibition on the use of alcohol or drugs under a DOT agency regulation constitutes a DOT drug and alcohol regulation violation.

§ 40.287

What information is an employer required to provide concerning SAP services to an employee who has a DOT drug and alcohol regulation violation?

As an employer, you must provide to each employee (including an applicant or new employee) who violates a DOT drug and alcohol regulation a listing of SAPs readily available to the employee and acceptable to you, with names, addresses, and telephone numbers. You cannot charge the employee any fee for compiling or providing this list. You may provide this list yourself or through a C/TPA or other service agent.

§ 40.289

Are employers required to provide SAP and treatment services to employees?

- (a) As an employer, you are not required to provide a SAP evaluation or any subsequent recommended education or treatment for an employee who has violated a DOT drug and alcohol regulation.
- (b) However, if you offer that employee an opportunity to return to a DOT safety-sensitive duty following a violation, you must, before the employee again performs that duty, ensure that the employee receives an evaluation by a SAP meeting the requirements of §40.281 and that the employee successfully complies with the SAP's evaluation recommendations.
- (c) Payment for SAP evaluations and services is left for employers and employees to decide and may be governed by existing management-labor agreements and health care benefits.

§ 40.291

What is the role of the SAP in the evaluation, referral, and treatment process of an employee who has violated DOT agency drug and alcohol testing regulations?

- (a) As a SAP, you are charged with:
 - (1) Making a face-to-face clinical assessment and evaluation to determine what assistance is needed by the employee to resolve problems associated with alcohol and/or drug use;
 - (2) Referring the employee to an appropriate education and/or treatment program;
 - (3) Conducting a face-to-face follow-up evaluation to determine if the employee has actively participated in the education and/or treatment program and has demonstrated successful compliance with the initial assessment and evaluation recommendations;
 - (4) Providing the DER with a follow-up drug and/or alcohol testing plan for the employee; and
 - (5) Providing the employee and employer with recommendations for continuing education and/or treatment.
- (b) As a SAP, you are not an advocate for the employer or employee. Your function is to protect the public interest in safety by professionally evaluating the employee and recommending appropriate education/treatment, follow-up tests, and aftercare.

§ 40.293

What is the SAP's function in conducting the initial evaluation of an employee?

As a SAP, for every employee who comes to you following a DOT drug and alcohol regulation violation, you must accomplish the following:

- (a) Provide a comprehensive face-to-face assessment and clinical evaluation.
- (b) Recommend a course of education and/or treatment with which the employee must demonstrate successful compliance prior to returning to DOT safety-sensitive duty.
 - (1) You must make such a recommendation for every individual who has violated a DOT drug and alcohol regulation.
 - (2) You must make a recommendation for education and/or treatment that will, to the greatest extent possible, protect public safety in the event that the employee returns to the performance of safety-sensitive functions.
- (c) Appropriate education may include, but is not limited to, self-help groups (e.g., Alcoholics Anonymous) and community lectures, where attendance can be independently verified, and bona fide drug and alcohol education courses.
- (d) Appropriate treatment may include, but is not limited to, in-patient hospitalization, partial in-patient treatment, out-patient counseling programs, and aftercare.
- (e) You must provide a written report directly to the DER highlighting your specific recommendations for assistance (see §40.311(c)).
- (f) For purposes of your role in the evaluation process, you must assume that a verified positive test result has conclusively

established that the employee committed a DOT drug and alcohol regulation violation. You must not take into consideration in any way, as a factor in determining what your recommendation will be, any of the following:

- (1) A claim by the employee that the test was unjustified or inaccurate;
- (2) Statements by the employee that attempt to mitigate the seriousness of a violation of a DOT drug or alcohol regulation (e.g., related to assertions of use of hemp oil, "medical marijuana" use, "contact positives," poppy seed ingestion, job stress); or
- (3) Personal opinions you may have about the justification or rationale for drug and alcohol testing.
- (g) In the course of gathering information for purposes of your evaluation in the case of a drug-related violation, you may consult with the MRO. As the MRO, you are required to cooperate with the SAP and provide available information the SAP requests. It is not necessary to obtain the consent of the employee to provide this information.

§ 40.295

May employees or employers seek a second SAP evaluation if they disagree with the first SAP's recommendations?

- (a) As an employee with a DOT drug and alcohol regulation violation, when you have been evaluated by a SAP, you must not seek a second SAP's evaluation in order to obtain another recommendation.
- (b) As an employer, you must not seek a second SAP's evaluation if the employee has already been evaluated by a qualified SAP. If the employee, contrary to paragraph (a) of this section, has obtained a second SAP evaluation, as an employer you may not rely on it for any purpose under this part.

§ 40.297

Does anyone have the authority to change a SAP's initial evaluation?

- (a) Except as provided in paragraph (b) of this section, no one (e.g., an employer, employee, a managed-care provider, any service agent) may change in any way the SAP's evaluation or recommendations for assistance. For example, a third party is not permitted to make more or less stringent a SAP's recommendation by changing the SAP's evaluation or seeking another SAP's evaluation.
- (b) The SAP who made the initial evaluation may modify his or her initial evaluation and recommendations based on new or additional information (e.g., from an education or treatment program).

§ 40.299

What is the SAP's role and what are the limits on a SAP's discretion in referring employees for education and treatment?

- (a) As a SAP, upon your determination of the best recommendation for assistance, you will serve as a referral source to assist the

employee's entry into a education and/or treatment program.

- (b) To prevent the appearance of a conflict of interest, you must not refer an employee requiring assistance to your private practice or to a person or organization from which you receive payment or to a person or organization in which you have a financial interest. You are precluded from making referrals to entities with which you are financially associated.
- (c) There are four exceptions to the prohibitions contained in paragraph (b) of this section. You may refer an employee to any of the following providers of assistance, regardless of your relationship with them:
 - (1) A public agency (e.g., treatment facility) operated by a state, county, or municipality;
 - (2) The employer or a person or organization under contract to the employer to provide alcohol or drug treatment and/or education services (e.g., the employer's contracted treatment provider);
 - (3) The sole source of therapeutically appropriate treatment under the employee's health insurance program (e.g., the single substance abuse in-patient treatment program made available by the employee's insurance coverage plan); or
 - (4) The sole source of therapeutically appropriate treatment reasonably available to the employee (e.g., the only treatment facility or education program reasonably located within the general commuting area).

§ 40.301

What is the SAP's function in the follow-up evaluation of an employee?

- (a) As a SAP, after you have prescribed assistance under §40.293, you must re-evaluate the employee to determine if the employee has successfully carried out your education and/or treatment recommendations.
 - (1) This is your way to gauge for the employer the employee's ability to demonstrate successful compliance with the education and/or treatment plan.
 - (2) Your evaluation may serve as one of the reasons the employer decides to return the employee to safety-sensitive duty.
- (b) As the SAP making the follow-up evaluation determination, you must:
 - (1) Confer with or obtain appropriate documentation from the appropriate education and/or treatment program professionals where the employee was referred; and
 - (2) Conduct a face-to-face clinical interview with the employee to determine if the employee demonstrates successful compliance with your initial evaluation recommendations.
- (c) (1) If the employee has demonstrated successful compliance, you must provide a written report directly to the DER highlighting your clinical determination that the employee has done so with your

- initial evaluation recommendation (see §40.311(d)).
- (2) You may determine that an employee has successfully demonstrated compliance even though the employee has not yet completed the full regimen of education and/or treatment you recommended or needs additional assistance. For example, if the employee has successfully completed the 30-day in-patient program you prescribed, you may make a "successful compliance" determination even though you conclude that the employee has not yet completed the out-patient counseling you recommended or should continue in an aftercare program.
- (d) (1) As the SAP, if you believe, as a result of the follow-up evaluation, that the employee has not demonstrated successful compliance with your recommendations, you must provide written notice directly to the DER (see §40.311(e)).
- (2) As an employer who receives the SAP's written notice that the employee has not successfully complied with the SAP's recommendations, you must not return the employee to the performance of safety-sensitive duties.
- (3) As the SAP, you may conduct additional follow-up evaluation(s) if the employer determines that doing so is consistent with the employee's progress as you have reported it and with the employer's policy and/or labor-management agreements.
- (4) As the employer, following a SAP report that the employee has not demonstrated successful compliance, you may take personnel action consistent with your policy and/or labor-management agreements.

§ 40.303
What happens if the SAP believes the employee needs additional treatment, aftercare, or support group services even after the employee returns to safety-sensitive duties?

- (a) As a SAP, if you believe that ongoing services (in addition to follow-up tests) are needed to assist an employee to maintain sobriety or abstinence from drug use after the employee resumes the performance of safety-sensitive duties, you must provide recommendations for these services in your follow-up evaluation report (see §40.311(d)(10)).
- (b) As an employer receiving a recommendation for these services from a SAP, you may, as part of a return-to-duty agreement with the employee, require the employee to participate in the recommended services. You may monitor and document the employee's participation in the recommended services. You may also make use of SAP and employee assistance program (EAP) services in assisting and monitoring employees' compliance with SAP recommendations. Nothing in this section permits an employer to fail to carry

- out its obligations with respect to follow-up testing (see §40.309).
- (c) As an employee, you are obligated to comply with the SAP's recommendations for these services. If you fail or refuse to do so, you may be subject to disciplinary action by your employer.

§ 40.305
How does the return-to-duty process conclude?

- (a) As the employer, if you decide that you want to permit the employee to return to the performance of safety-sensitive functions, you must ensure that the employee takes a return-to-duty test. This test cannot occur until after the SAP has determined that the employee has successfully complied with prescribed education and/or treatment. The employee must have a negative drug test result and/or an alcohol test with an alcohol concentration of less than 0.02 before resuming performance of safety-sensitive duties.
- (b) As an employer, you must not return an employee to safety-sensitive duties until the employee meets the conditions of paragraph (a) of this section. However, you are not required to return an employee to safety-sensitive duties because the employee has met these conditions. That is a personnel decision that you have the discretion to make, subject to collective bargaining agreements or other legal requirements.
- (c) As a SAP or MRO, you must not make a "fitness for duty" determination as part of this re-evaluation unless required to do so under an applicable DOT agency regulation. It is the employer, rather than you, who must decide whether to put the employee back to work in a safety-sensitive position.

§ 40.307
What is the SAP's function in prescribing the employee's follow-up tests?

- (a) As a SAP, for each employee who has committed a DOT drug or alcohol regulation violation, and who seeks to resume the performance of safety-sensitive functions, you must establish a written follow-up testing plan. You do not establish this plan until after you determine that the employee has successfully complied with your recommendations for education and/or treatment.
- (b) You must present a copy of this plan directly to the DER (see §40.311(d)(9)).
- (c) You are the sole determiner of the number and frequency of follow-up tests and whether these tests will be for drugs, alcohol, or both, unless otherwise directed by the appropriate DOT agency regulation. For example, if the employee had a positive drug test, but your evaluation or the treatment program professionals determined that the employee had an alcohol problem as well, you should require that the employee have follow-up tests for both drugs and alcohol.
- (d) However, you must, at a minimum, direct that the employee be subject to six unannounced follow-up tests in the first 12 months of safety-sensitive duty following

the employee's return to safety-sensitive functions.

- (1) You may require a greater number of follow-up tests during the first 12-month period of safety-sensitive duty (e.g., you may require one test a month during the 12-month period; you may require two tests per month during the first 6-month period and one test per month during the final 6-month period).
- (2) You may also require follow-up tests during the 48 months of safety-sensitive duty following this first 12-month period.
- (3) You are not to establish the actual dates for the follow-up tests you prescribe. The decision on specific dates to test is the employer's.
- (4) As the employer, you must not impose additional testing requirements (e.g., under company authority) on the employee that go beyond the SAP's follow-up testing plan.
- (e) The requirements of the SAP's follow-up testing plan "follow the employee" to subsequent employers or through breaks in service.

Example 1 to Paragraph (e):

The employee returns to duty with Employer A. Two months afterward, after completing the first two of six follow-up tests required by the SAP's plan, the employee quits his job with Employer A and begins to work in a similar position for Employer B. The employee remains obligated to complete the four additional tests during the next 10 months of safety-sensitive duty, and Employer B is responsible for ensuring that the employee does so. Employer B learns of this obligation through the inquiry it makes under §40.25.

Example 2 to Paragraph (e):

The employee returns to duty with Employer A. Three months later, after the employee completes the first two of six follow-up tests required by the SAP's plan, Employer A lays the employee off for economic or seasonal employment reasons. Four months later, Employer A recalls the employee. Employer A must ensure that the employee completes the remaining four follow-up tests during the next nine months.

- (f) As the SAP, you may modify the determinations you have made concerning follow-up tests. For example, even if you recommended follow-up testing beyond the first 12-months, you can terminate the testing requirement at any time after the first year of testing. You must not, however, modify the requirement that the employee take at least six follow-up tests within the first 12 months after returning to the performance of safety-sensitive functions.

§ 40.309
What are the employer's responsibilities with respect to the SAP's directions for follow-up tests?

- (a) As the employer, you must carry out the SAP's follow-up testing requirements. You may not allow the employee to continue to perform safety-sensitive functions unless

follow-up testing is conducted as directed by the SAP.

- (b) You should schedule follow-up tests on dates of your own choosing, but you must ensure that the tests are unannounced with no discernable pattern as to their timing, and that the employee is given no advance notice.
- (c) You cannot substitute any other tests (e.g., those carried out under the random testing program) conducted on the employee for this follow-up testing requirement.
- (d) You cannot count a follow-up test that has been cancelled as a completed test. A cancelled follow-up test must be recollected.

§ 40.311

What are the requirements concerning SAP reports?

- (a) As the SAP conducting the required evaluations, you must send the written reports required by this section in writing directly to the DER and not to a third party or entity for forwarding to the DER (except as provided in §40.355(e)). You may, however, forward the document simultaneously to the DER and to a C/TPA.
- (b) As an employer, you must ensure that you receive SAP written reports directly from the SAP performing the evaluation and that no third party or entity changed the SAP's report in any way.
- (c) The SAP's written report, following an initial evaluation that determines what level of assistance is needed to address the employee's drug and/or alcohol problems, must be on the SAP's own letterhead (and not the letterhead of another service agent) signed and dated by the SAP, and must contain the following delineated items:
 - (1) Employee's name and SSN;
 - (2) Employer's name and address;
 - (3) Reason for the assessment (specific violation of DOT regulations and violation date);
 - (4) Date(s) of the assessment;
 - (5) SAP's education and/or treatment recommendation; and
 - (6) SAP's telephone number.
- (d) The SAP's written report concerning a follow-up evaluation that determines the employee has demonstrated successful compliance must be on the SAP's own letterhead (and not the letterhead of another service agent), signed by the SAP and dated, and must contain the following items:
 - (1) Employee's name and SSN;
 - (2) Employer's name and address;
 - (3) Reason for the initial assessment (specific violation of DOT regulations and violation date);
 - (4) Date(s) of the initial assessment and synopsis of the treatment plan;
 - (5) Name of practice(s) or service(s) providing the recommended education and/or treatment;
 - (6) Inclusive dates of employee's program participation;
 - (7) Clinical characterization of employee's program participation;
 - (8) SAP's clinical determination as to whether the employee has demonstrated successful compliance;

- (9) Follow-up testing plan;
- (10) Employee's continuing care needs with specific treatment, aftercare, and/or support group services recommendations; and
- (11) SAP's telephone number.
- (e) The SAP's written report concerning a follow-up evaluation that determines the employee has not demonstrated successful compliance must be on the SAP's own letterhead (and not the letterhead of another service agent), signed by the SAP and dated, and must contain the following items:
 - (1) Employee's name and SSN;
 - (2) Employer's name and address;
 - (3) Reason for the initial assessment (specific DOT violation and date);
 - (4) Date(s) of initial assessment and synopsis of treatment plan;
 - (5) Name of practice(s) or service(s) providing the recommended education and/or treatment;
 - (6) Inclusive dates of employee's program participation;
 - (7) Clinical characterization of employee's program participation;
 - (8) Date(s) of the first follow-up evaluation;
 - (9) Date(s) of any further follow-up evaluation the SAP has scheduled;
 - (10) SAP's clinical reasons for determining that the employee has not demonstrated successful compliance; and
 - (11) SAP's telephone number.
- (f) As a SAP, you must also provide these written reports directly to the employee if the employee has no current employer and to the gaining DOT regulated employer in the event the employee obtains another transportation industry safety-sensitive position.
- (g) As a SAP, you are to maintain copies of your reports to employers for 5 years, and your employee clinical records in accordance with Federal, state, and local laws regarding record maintenance, confidentiality, and release of information. You must make these records available, on request, to DOT agency representatives (e.g., inspectors conducting an audit or safety investigation) and representatives of the NTSB in an accident investigation.
- (h) As an employer, you must maintain your reports from SAPs for 5 years from the date you received them.

§ 40.313

Where is other information on SAP functions and the return-to-duty process found in this regulation?

You can find other information on the role and functions of SAPs in the following sections of this part:

- §40.3 Definition.
- §40.347 Service agent assistance with SAP-required follow-up testing.
- §40.355 Transmission of SAP reports.
- §40.329(c) Making SAP reports available to employees on request.
- Appendix E to Part 40
SAP Equivalency Requirements for Certification Organizations.

Subpart P - Confidentiality and Release of Information

§ 40.321

What is the general confidentiality rule for drug and alcohol test information?

Except as otherwise provided in this subpart, as a service agent or employer participating in the DOT drug or alcohol testing process, you are prohibited from releasing individual test results or medical information about an employee to third parties without the employee's specific written consent.

- (a) A "third party" is any person or organization to whom other subparts of this regulation do not explicitly authorize or require the transmission of information in the course of the drug or alcohol testing process.
- (b) "Specific written consent" means a statement signed by the employee that he or she agrees to the release of a particular piece of information to a particular, explicitly identified, person or organization at a particular time. "Blanket releases," in which an employee agrees to a release of a category of information (e.g., all test results) or to release information to a category of parties (e.g., other employers who are members of a C/TPA, companies to which the employee may apply for employment), are prohibited under this part.

§ 40.323

May program participants release drug or alcohol test information in connection with legal proceedings?

- (a) As an employer, you may release information pertaining to an employee's drug or alcohol test without the employee's consent in certain legal proceedings.
 - (1) These proceedings include a lawsuit (e.g., a wrongful discharge action), grievance (e.g., an arbitration concerning disciplinary action taken by the employer), or administrative proceeding (e.g., an unemployment compensation hearing) brought by, or on behalf of, an employee and resulting from a positive DOT drug or alcohol test or a refusal to test (including, but not limited to, adulterated or substituted test results).
 - (2) These proceedings also include a criminal or civil action resulting from an employee's performance of safety-sensitive duties, in which a court of competent jurisdiction determines that the drug or alcohol test information sought is relevant to the case and issues an order directing the employer to produce the information. For example, in personal injury litigation following a truck or bus collision, the court could determine that a post-accident drug test result of an employee is relevant to determining whether the driver or the driver's employer was negligent. The employer is authorized to respond to the court's order to produce the records.
- (b) In such a proceeding, you may release the information to the decisionmaker in the proceeding (e.g., the court in a lawsuit). You may release the information only with

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a binding stipulation that the decisionmaker to whom it is released will make it available only to parties to the proceeding.

- (c) If you are a service agent, and the employer requests its employee's drug or alcohol testing information from you to use in a legal proceeding as authorized in paragraph (a) of this section (e.g., the laboratory's data package), you must provide the requested information to the employer.
- (d) As an employer or service agent, you must immediately notify the employee in writing of any information you release under this section.

§ 40.327

When must the MRO report medical information gathered in the verification process?

- (a) As the MRO, you must, except as provided in paragraph (c) of this section, report drug test results and medical information you learned as part of the verification process to third parties without the employee's consent if you determine, in your reasonable medical judgment, that:
 - (1) The information is likely to result in the employee being determined to be medically unqualified under an applicable DOT agency regulation; or
 - (2) The information indicates that continued performance by the employee of his or her safety-sensitive function is likely to pose a significant safety risk.
- (b) The third parties to whom you are authorized to provide information by this section include the employer, a physician or other health care provider responsible for determining the medical qualifications of the employee under an applicable DOT agency safety regulation, a SAP evaluating the employee as part of the return to duty process (see §40.293(g)), a DOT agency, or the National Transportation Safety Board in the course of an accident investigation.
- (c) If the law of a foreign country (e.g., Canada) prohibits you from providing medical information to the employer, you may comply with that prohibition.

§ 40.329

What information must laboratories, MROs, and other service agents release to employees?

- (a) As an MRO or service agent you must provide, within 10 business days of receiving a written request from an employee, copies of any records pertaining to the employee's use of alcohol and/or drugs, including records of the employee's DOT-mandated drug and/or alcohol tests. You may charge no more than the cost of preparation and reproduction for copies of these records.
- (b) As a laboratory, you must provide, within 10 business days of receiving a written request from an employee, and made through the MRO, the records relating to the results of the employee's drug test (i.e., laboratory report and data package). You may charge no more than the cost of preparation and reproduction for copies of these records.
- (c) As a SAP, you must make available to an employee, on request, a copy of all SAP

reports (see §40.311). However, you must redact follow-up testing information from the report before providing it to the employee.

[65 FR 79526, Dec. 19, 2000, as amended at 66 FR 41954, Aug. 9, 2001]

§ 40.331 To what additional parties must employers and service agents release information?

As an employer or service agent you must release information under the following circumstances:

- (a) If you receive a specific, written consent from an employee authorizing the release of information about that employee's drug or alcohol tests to an identified person, you must provide the information to the identified person. For example, as an employer, when you receive a written request from a former employee to provide information to a subsequent employer, you must do so. In providing the information, you must comply with the terms of the employee's consent.
- (b) If you are an employer, you must, upon request of DOT agency representatives, provide the following:
 - (1) Access to your facilities used for this part and DOT agency drug and alcohol program functions.
 - (2) All written, printed, and computer-based drug and alcohol program records and reports (including copies of name-specific records or reports), files, materials, data, documents/documentation, agreements, contracts, policies, and statements that are required by this part and DOT agency regulations. You must provide this information at your principal place of business in the time required by the DOT agency.
 - (3) All items in paragraph (b)(2) of this section must be easily accessible, legible, and provided in an organized manner. If electronic records do not meet these standards, they must be converted to printed documentation that meets these standards.
- (c) If you are a service agent, you must, upon request of DOT agency representatives, provide the following:
 - (1) Access to your facilities used for this part and DOT agency drug and alcohol program functions.
 - (2) All written, printed, and computer-based drug and alcohol program records and reports (including copies of name-specific records or reports), files, materials, data, documents/documentation, agreements, contracts, policies, and statements that are required by this part and DOT agency regulations. You must provide this information at your principal place of business in the time required by the DOT agency.
 - (3) All items in paragraph (c)(2) of this section must be easily accessible, legible, and provided in an organized manner. If electronic records do not meet these standards, they must be converted to printed documentation that meets these standards.

- (d) If requested by the National Transportation Safety Board as part of an accident investigation, you must provide information concerning post-accident tests administered after the accident.
- (e) If requested by a Federal, state or local safety agency with regulatory authority over you or the employee, you must provide drug and alcohol test records concerning the employee.
- (f) Except as otherwise provided in this part, as a laboratory you must not release or provide a specimen or a part of a specimen to a requesting party, without first obtaining written consent from ODAPC. If a party seeks a court order directing you to release a specimen or part of a specimen contrary to any provision of this part, you must take necessary legal steps to contest the issuance of the order (e.g., seek to quash a subpoena, citing the requirements of §40.13). This part does not require you to disobey a court order, however.
- (g) Notwithstanding any other provision of this Part, as an employer of Commercial Motor Vehicle (CMV) drivers holding commercial driving licenses (CDLs) or as a third party administrator for owner-operator CMV drivers with CDLs, you are authorized to comply with State laws requiring you to provide to State CDL licensing authorities information about all violations of DOT drug and alcohol testing rules (including positive tests and refusals) by any CMV driver holding a CDL.

[65 FR 79526, Dec. 19, 2000, as amended at 66 FR 41955, Aug. 9, 2001; 73 FR 33737, June 13, 2008, February 25, 2010]

§ 40.333

What records must employers keep?

- (a) As an employer, you must keep the following records for the following periods of time:
 - (1) You must keep the following records for five years:
 - (i) Records of alcohol test results indicating an alcohol concentration of 0.02 or greater;
 - (ii) Records of verified positive drug test results;
 - (iii) Documentation of refusals to take required alcohol and/or drug tests (including substituted or adulterated drug test results);
 - (iv) SAP reports; and
 - (v) All follow-up tests and schedules for follow-up tests.
 - (2) You must keep records for three years of information obtained from previous employers under §40.25 concerning drug and alcohol test results of employees.
 - (3) You must keep records of the inspection, maintenance, and calibration of EBTs, for two years.
 - (4) You must keep records of negative and cancelled drug test results and alcohol test results with a concentration of less than 0.02 for one year.
- (b) You do not have to keep records related to a program requirement that does not apply to you (e.g., a maritime employer who does not have a DOT-mandated random alcohol testing program need not maintain random alcohol testing records).

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- (c) You must maintain the records in a location with controlled access.
- (d) A service agent may maintain these records for you. However, you must ensure that you can produce these records at your principal place of business in the time required by the DOT agency. For example, as a motor carrier, when an FMCSA inspector requests your records, you must ensure that you can provide them within two business days.
- (e) If you store records electronically, where permitted by this part, you must ensure that the records are easily accessible, legible, and formatted and stored in an organized manner. If electronic records do not meet these criteria, you must convert them to printed documentation in a rapid and readily auditable manner, at the request of DOT agency personnel.

[65 FR 79526, Dec. 19, 2000, as amended at 66 FR 41955, Aug. 9, 2001]

Subpart Q - Roles and Responsibilities of Service Agents

§ 40.341

Must service agents comply with DOT drug and alcohol testing requirements?

- (a) As a service agent, the services you provide to transportation employers must meet the requirements of this part and the DOT agency drug and alcohol testing regulations.
- (b) If you do not comply, DOT may take action under the Public Interest Exclusions procedures of this part (see Subpart R of this part) or applicable provisions of other DOT agency regulations.

§ 40.343

What tasks may a service agent perform for an employer?

As a service agent, you may perform for employers the tasks needed to comply with DOT agency drug and alcohol testing regulations, subject to the requirements and limitations of this part.

§ 40.345

In what circumstances may a C/TPA act as an intermediary in the transmission of drug and alcohol testing information to employers?

- (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).
- (b) The specific provisions of this part concerning which you may act as an intermediary are listed in Appendix F to this part. These are the only situations in which you may act as an intermediary. You are prohibited from doing so in all other situations.
- (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.

§ 40.347

What functions may C/TPAs perform with respect to administering testing?

As a C/TPA, except as otherwise specified in this part, you may perform the following functions for employers concerning random selection and other selections for testing.

- (a) You may operate random testing programs for employers and may assist (i.e., through contracting with laboratories or collection sites, conducting collections) employers with other types of testing (e.g., pre-employment, post-accident, reasonable suspicion, return-to-duty, and follow-up).
- (b) You may combine employees from more than one employer or one transportation industry in a random pool if permitted by all the DOT agency drug and alcohol testing regulations involved.
 - (1) If you combine employees from more than one transportation industry, you must ensure that the random testing rate is at least equal to the highest rate required by each DOT agency.
 - (2) Employees not covered by DOT agency regulations may not be part of the same random pool with DOT covered employees.
- (c) You may assist employers in ensuring that follow-up testing is conducted in accordance with the plan established by the SAP. However, neither you nor the employer are permitted to randomly select employees from a "follow-up pool" for follow-up testing.

§ 40.349

What records may a service agent receive and maintain?

- (a) Except where otherwise specified in this part, as a service agent you may receive and maintain all records concerning DOT drug and alcohol testing programs, including positive, negative, and refusal to test individual test results. You do not need the employee's consent to receive and maintain these records.
- (b) You may maintain all information needed for operating a drug/alcohol program (e.g., CCFs, ATFs, names of employees in random pools, random selection lists, copies of notices to employers of selected employees) on behalf of an employer.
- (c) If a service agent originating drug or alcohol testing information, such as an MRO or BAT, sends the information directly to the DER, he or she may also provide the information simultaneously to you, as a C/TPA or other service agent who maintains this information for the employer.
- (d) If you are serving as an intermediary in transmitting information that is required to

be provided to the employer, you must ensure that it reaches the employer in the same time periods required elsewhere in this part.

- (e) You must ensure that you can make available to the employer within two business days any information the employer is asked to produce by a DOT agency representative.
- (f) On request of an employer, you must, at any time on the request of an employer, transfer immediately all records pertaining to the employer and its employees to the employer or to any other service agent the employer designates. You must carry out this transfer as soon as the employer requests it. You are not required to obtain employee consent for this transfer. You must not charge more than your reasonable administrative costs for conducting this transfer. You may not charge a fee for the release of these records.
- (g) If you are planning to go out of business or your organization will be bought by or merged with another organization, you must immediately notify all employers and offer to transfer all records pertaining to the employer and its employees to the employer or to any other service agent the employer designates. You must carry out this transfer as soon as the employer requests it. You are not required to obtain employee consent for this transfer. You must not charge more than your reasonable administrative costs for conducting this transfer. You may not charge a fee for the release of these records.

[65 FR 79526, Dec. 19, 2000, as amended at 66 FR 41955, Aug. 9, 2001]

§ 40.351

What confidentiality requirements apply to service agents?

Except where otherwise specified in this part, as a service agent the following confidentiality requirements apply to you:

- (a) When you receive or maintain confidential information about employees (e.g., individual test results), you must follow the same confidentiality regulations as the employer with respect to the use and release of this information.
- (b) You must follow all confidentiality and records retention requirements applicable to employers.
- (c) You may not provide individual test results or other confidential information to another employer without a specific, written consent from the employee. For example, suppose you are a C/TPA that has employers X and Y as clients. Employee Jones works for X, and you maintain Jones' drug and alcohol test for X. Jones wants to change jobs and work for Y. You may not inform Y of the result of a test conducted for X without having a specific, written consent from Jones. Likewise, you may not provide this information to employer Z, who is not a C/TPA member, without this consent.
- (d) You must not use blanket consent forms authorizing the release of employee testing information.
- (e) You must establish adequate confidentiality and security measures to ensure that

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confidential employee records are not available to unauthorized persons. This includes protecting the physical security of records, access controls, and computer security measures to safeguard confidential data in electronic data bases.

§ 40.353

What principles govern the interaction between MROs and other service agents?

As a service agent other than an MRO (e.g., a C/TPA), the following principles govern your interaction with MROs:

- (a) You may provide MRO services to employers, directly or through contract, if you meet all applicable provisions of this part.
- (b) If you employ or contract for an MRO, the MRO must perform duties independently and confidentially. When you have a relationship with an MRO, you must structure the relationship to ensure that this independence and confidentiality are not compromised. Specific means (including both physical and operational measures, as appropriate) to separate MRO functions and other service agent functions are essential.
- (c) Only your staff who are actually under the day-to-day supervision and control of an MRO with respect to MRO functions may perform these functions. This does not mean that those staff may not perform other functions at other times. However, the designation of your staff to perform MRO functions under MRO supervision must be limited and not used as a subterfuge to circumvent confidentiality and other requirements of this part and DOT agency regulations. You must ensure that MRO staff operate under controls sufficient to ensure that the independence and confidentiality of the MRO process are not compromised.
- (d) Like other MROs, an MRO you employ or contract with must personally conduct verification interviews with employees and must personally make all verification decisions. Consequently, your staff cannot perform these functions.

§ 40.355

What limitations apply to the activities of service agents?

As a service agent, you are subject to the following limitations concerning your activities in the DOT drug and alcohol testing program.

- (a) You must not require an employee to sign a consent, release, waiver of liability, or indemnification agreement with respect to any part of the drug or alcohol testing process covered by this part (including, but not limited to, collections, laboratory testing, MRO, and SAP services). No one may do so on behalf of a service agent.
- (b) You must not act as an intermediary in the transmission of drug test results from the laboratory to the MRO. That is, the laboratory may not send results to you, with you in turn sending them to the MRO for verification. For example, a practice in which the laboratory transmits results to your computer system, and you then assign the results to a particular MRO, is not permitted.

- (c) You must not transmit drug test results directly from the laboratory to the employer (by electronic or other means) or to a service agent who forwards them to the employer. All confirmed laboratory results must be processed by the MRO before they are released to any other party.
- (d) You must not act as an intermediary in the transmission of alcohol test results of 0.02 or higher from the STT or BAT to the DER.
- (e) Except as provided in paragraph (f) of this section, you must not act as an intermediary in the transmission of individual SAP reports to the actual employer. That is, the SAP may not send such reports to you, with you in turn sending them to the actual employer. However, you may maintain individual SAP summary reports and follow-up testing plans after they are sent to the DER, and the SAP may transmit such reports to you simultaneously with sending them to the DER.
- (f) As an exception to paragraph (e) of this section, you may act as an intermediary in the transmission of SAP report from the SAP to an owner-operator or other self-employed individual.
- (g) Except as provided in paragraph (h) of this section, you must not make decisions to test an employee based upon reasonable suspicion, post-accident, return-to-duty, and follow-up determination criteria. These are duties the actual employer cannot delegate to a C/TPA. You may, however, provide advice and information to employers regarding these testing issues and how the employer should schedule required testing.
- (h) As an exception to paragraph (g) of this section, you may make decisions to test an employee based upon reasonable suspicion, post-accident, return-to-duty, and follow-up determination criteria with respect to an owner-operator or other self-employed individual.
- (i) Except as provided in paragraph (j) of this section, you must not make a determination that an employee has refused a drug or alcohol test. This is a non-delegable duty of the actual employer. You may, however, provide advice and information to employers regarding refusal-to-test issues.
- (j) As an exception to paragraph (i) of this section, you may make a determination that an employee has refused a drug or alcohol test, if:
 - (1) You schedule a required test for an owner-operator or other self-employed individual, and the individual fails to appear for the test without a legitimate reason; or
 - (2) As an MRO, you determine that an individual has refused to test on the basis of adulteration or substitution.
- (k) You must not act as a DER. For example, while you may be responsible for transmitting information to the employer about test results, you must not act on behalf of the employer in actions to remove employees from safety-sensitive duties.
- (l) In transmitting documents to laboratories, you must ensure that you send to the laboratory that conducts testing only Copy 1 of the CCF. You must not transmit other

copies of the CCF or any ATFs to the laboratory.

- (m) You must not impose conditions or requirements on employers that DOT regulations do not authorize. For example, as a C/TPA serving employers in the pipeline or motor carrier industry, you must not require employers to have provisions in their DOT plans that PHMSA or FMCSA regulations do not require.
- (n) You must not intentionally delay the transmission of drug or alcohol testing-related documents concerning actions you have performed, because of a payment dispute or other reasons.

Example 1 to Paragraph (n):

A laboratory that has tested a specimen must not delay transmitting the documentation of the test result to an MRO because of a billing or payment dispute with the MRO or a C/TPA.

Example 2 to Paragraph (n):

An MRO or SAP who has interviewed an employee must not delay sending a verified test result or SAP report to the employer because of such a dispute with the employer or employee.

Example 3 to Paragraph (n):

A collector who has performed a urine specimen collection must not delay sending the drug specimen and CCF to the laboratory because of a payment or other dispute with the laboratory or a C/TPA.

Example 4 to Paragraph (n):

A BAT who has conducted an alcohol test must not delay sending test result information to an employer or C/TPA because of a payment or other dispute with the employer or C/TPA.

- (o) While you must follow the DOT agency regulations, the actual employer remains accountable to DOT for compliance, and your failure to implement any aspect of the program as required in this part and other applicable DOT agency regulations makes the employer subject to enforcement action by the Department.

[65 FR 79526, Dec. 19, 2000, as amended at 66 FR 41955, Aug. 9, 2001; 75 FR 59108, September 27, 2010]

Subpart R - Public Interest Exclusions