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Appendix G to Part 40–Alcohol Testing Form (ATF)

[53 FR 47002, Nov. 21, 1988 as amended by Amdt. 40-1, 54 FR 49854, Dec. 1, 1989; Amdt. 40-2, 59 FR 7340, Feb. 15, 1994; Amdt. 40-5, 60 FR 19675, Apr. 20, 1995; Amdt. 40-8, 61 FR 37693, July 19, 1996; Amdt. 40-10, 65 FR 79462, Dec. 19, 2000 as amended by a second effective date in Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

Authority: 49 U.S.C. 102, 301, 322, 5331, 20140, 31306, and 45101 et seq.

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).

[53 FR 47002, Nov. 21, 1988 as amended by Amdt. 40-1, 54 FR 49854, Dec. 1, 1989; Amdt. 40-2, 59 FR 7340, Feb. 15, 1994; Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§40.2 [Removed]

[53 FR 47002, Nov. 21, 1988; removed by Amdt. 40-1, 54 FR 49854, Dec. 1, 1989]

§40.3 What do the terms used in this regulation mean?

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

Adulterated specimen. A specimen that contains a substance that is not expected to be present in human urine, or contains a substance expected to be present but is at a

concentration so high that it is not consistent with human urine.

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.

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).

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.

Confirmation (or confirmatory) drug test. A second analytical procedure performed on a urine specimen to identify and quantify the presence of a specific drug or drug metabolite.

Confirmation (or confirmatory) validity test. A second test performed on a 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 for medical review officers (MROs) and substance abuse professionals (SAPs) who have completed qualification training and are performing MRO or SAP functions, designed to keep MROs and 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 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 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 Research and Special Programs Administration (RSPA), 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 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. The test used to differentiate a negative specimen from one that requires further testing for drugs or drug metabolites.

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

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. (The HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs are available on the internet at http://www.health.org/workpl.htm or from the Division of Workplace Programs, 5600 Fishers Lane, Rockwall II Building, Suite 815, Rockville, MD 20857.)

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.

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.

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).

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).

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.

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 specimen with creatinine and specific gravity values that are so diminished that they are not consistent with 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.

[53 FR 47002, Nov. 21, 1988 as amended by Amdt. 40-1, 54 FR 49854, Dec. 1, 1989; Amdt. 40-2, 59 FR 7340, Feb. 15, 1994; Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§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.

[Amdt. 40-1, 54 FR 49854, Dec. 1, 1989 as amended by Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

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

(a) 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.

(b) Under the standards of 49 CFR part 5, we will grant the request only if the request documents special or exceptional 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.

[Amdt. 40-1, 54 FR 49854, Dec. 1, 1989 as amended by Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

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.

[Amdt. 40-1, 54 FR 49854, Dec. 1, 1989 as amended by Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§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.

[Amdt. 40-1, 54 FR 49854, Dec. 1, 1989 as amended by Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§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.

[Amdt. 40-1, 54 FR 49854, Dec. 1, 1989 as amended by Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§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.

[Amdt. 40-1, 54 FR 49854, Dec. 1, 1989 as amended by Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§40.19 [Reserved]

[Amdt. 40-1, 54 FR 49854, Dec. 1, 1989

§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 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.

[53 FR 47002, Nov. 21, 1988 as amended by Amdt. 40-1, 54 FR 49854, Dec. 1, 1989; Amdt. 40-2, 59 FR 7340, Feb. 15, 1994; Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§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 0.02–0.39, 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 specimen 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) as for the original collection.

(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.

[53 FR 47002, Nov. 21, 1988 as amended by Amdt. 40-1, 54 FR 49854, Dec. 1, 1989; Amdt. 40-2, 59 FR 7340, Feb. 15, 1994; Amdt. 40-3, 59 FR 42996, Aug. 19, 1994; Amdt. 40-8, 61 FR 37693, July 19, 1996; Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§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.

(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-do-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).

[53 FR 47002, Nov. 21, 1988 as amended by Amdt. 40-1, 54 FR 49854, Dec. 1, 1989; Amdt. 40-2, 59 FR 7340, Feb. 15, 1994; Amdt. 40-3, 59 FR 42996, Aug. 19, 1994; Amdt. 40-8, 61 FR 37693, July 19, 1996; Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§40.27 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.

[53 FR 47002, Nov. 21, 1988 as amended by Amdt. 40-1, 54 FR 49854, Dec. 1, 1989; Amdt. 40-2, 59 FR 7340, Feb. 15, 1994; Amdt. 40-3, 59 FR 42996, Aug. 19, 1994; Amdt. 40-9, 63 FR 65128, Nov. 25, 1998; Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

Subpart C–Urine Collection Personnel

§40.31 Who may collect urine specimens for DOT drug testing?

(a) Collectors meeting the requirements of this subpart are the only persons authorized to collect urine specimens for DOT drug testing.

(b) A collector must meet training requirements of §40.33.

(c) As the immediate supervisor of an employee being tested, you may not act as the collector when that employee is tested, unless no other collector is available and you are permitted to do so under DOT agency drug and alcohol regulations.

(d) You must not act as the collector for the employee being tested if you work for a HHS-certified laboratory (*e.g.*, as a technician or accessioner) and could link the employee with a urine specimen, drug testing result, or laboratory report.

[Amdt. 40-1, 54 FR 49854, Dec. 1, 1989; Amdt. 40-2, 59 FR 7340, Feb. 15, 1994; Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§40.33 What training requirements must a collector meet?

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

(a) *Basic information.* You must be knowledgeable about this part, the current "DOT Urine Specimen Collection Procedures Guidelines," and DOT agency regulations applicable to the employers for whom you perform collections, and you must keep current on any changes to these materials. The DOT Urine Specimen Collection Procedures Guidelines document is 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. Qualification training must provide instruction on the following subjects:

(1) All steps necessary to complete a collection correctly and the proper completion and transmission of the CCF;

(2) "Problem" collections (*e.g.*, situations like "shy bladder" and attempts to tamper with a specimen);

(3) Fatal flaws, correctable flaws, and how to correct problems in collections; and

(4) The collector's responsibility for maintaining the integrity of the collection process, ensuring the privacy of employees being tested, ensuring the security of the specimen, and avoiding conduct or statements that could be viewed as offensive or inappropriate;

(c) *Initial Proficiency Demonstration.* Following your completion of qualification training under paragraph (b) of this section, you must demonstrate proficiency in collections under this part by completing five consecutive error-free mock collections.

(1) The five mock collections must include two uneventful collection scenarios, one insufficient quantity of urine scenario, one temperature out of range scenario, and one scenario in which the employee refuses to sign the CCF and initial the specimen bottle tamper-evident seal.

(2) 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 has demonstrated necessary knowledge, skills, and abilities by–

(i) Regularly conducting DOT drug test collections for a period of at least a year;

(ii) Conducting collector training under this part for a year; or

(iii) Successfully completing a "train the trainer" course.

(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 collector before August 1, 2001, and you have already met the requirements of paragraphs (b) and (c) of this section, you do not have to meet them again.

(2) If you became a collector before August 1, 2001, and have yet to meet the requirements of paragraphs (b) and (c) of this section, you must do so no later than January 31, 2003.

(3) If you become a collector on or after August 1, 2001, you must meet the requirements of paragraphs (b) and (c) of this section before you begin to perform collector 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.

(f) *Error Correction Training*. If you make a mistake in the collection 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.

(i) Error correction training must be provided and your proficiency documented in writing by a person who meets the requirements of paragraph (c)(2) of this section.

(ii) 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.

(iii) As part of the error correction training, you must demonstrate your proficiency in the collection procedures of this part by completing three consecutive error-free mock collections. The mock collections 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 collections 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 using or negotiating to use your services.

[53 FR 47002, Nov. 21, 1988 as amended by Amdt. 40-1, 54 FR 49854, Dec. 1, 1989; Amdt. 40-2, 59 FR 7340, Feb. 15, 1994; Amdt. 40-8, 61 FR 37693, July 19, 1996; Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§40.35 What information about the DER must employers provide to collectors?

As an employer, you must provide to collectors 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.

[53 FR 47002, Nov. 21, 1988 as amended by Amdt. 40-1, 54 FR 49854, Dec. 1, 1989; Amdt. 40-2, 59 FR 7340, Feb. 15, 1994; Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§40.37 Where is other information on the role of collectors found in this regulation?

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

§40.3–Definition.
§40.43–Steps to prepare and secure collection sites.
§§ 40.45-40.47–Use of CCF.
§§ 40.49-40.51–Use of collection kit and shipping materials.
§§ 40.61-40.63–Preliminary steps in collections.
§40.65–Role in checking specimens.
§40.67–Role in directly observed collections.
§40.69–Role in monitored collections.
§40.71–Role in split specimen collections.
§40.73–Chain of custody completion and finishing the collection process.
§40.103–Processing blind specimens.
§40.191–Action in case of refusals to take test.
§40.193–Action in "shy bladder" situations.
§40.199-40.205–Collector errors in tests, effects, and means of correction.

[53 FR 47002, Nov. 21, 1988 as amended by Amdt. 40-2, 59 FR 7340, Feb. 15, 1994; Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§40.39 [Removed]

[Amdt. 40-1, 54 FR 49854, Dec. 1, 1989 as amended by Amdt. 40-2, 59 FR 7340, Feb. 15, 1994; Amdt. 40-6, 61 FR 37015, July 16, 1996; removed by Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

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

§40.41 Where does a urine collection for a DOT drug test take place?

(a) A urine collection for a DOT drug test must take place in a collection site meeting the requirements of this section.

(b) If you are operating a collection site, you must ensure that it meets the security requirements of §40.43.

(c) If you are operating a collection site, you must have all necessary personnel, materials, equipment, facilities and supervision to provide for the collection, temporary storage, and shipping of urine specimens to a laboratory, and a suitable clean surface for writing.

(d) Your collection site must include a facility for urination described in either paragraph (e) or paragraph (f) of this section.

(e) The first, and preferred, type of facility for urination that a collection site may include is a single-toilet room, having a full-length privacy door, within which urination can occur.

(1) No one but the employee may be present in the room during the collection, except for the observer in the event of a directly observed collection.

(2) You must have a source of water for washing hands, that, if practicable, should be external to the closed room where urination occurs. If an external source is not available, you may meet this requirement by securing all sources of water and other substances that could be used for adulteration and substitution (*e.g.*, water faucets, soap dispensers) and providing moist towelettes outside the closed room.

(f) The second type of facility for urination that a collection site may include is a multistall restroom.

(1) Such a site must provide substantial visual privacy (*e.g.*, a toilet stall with a partial-length door) and meet all other applicable requirements of this section.

(2) If you use a multi-stall restroom, you must either–

(i) Secure all sources of water and other substances that could be used for adulteration and substitution (*e.g.*, water faucets, soap dispensers) and place bluing agent in all toilets or secure the toilets to prevent access; or

(ii) Conduct all collections in the facility as monitored collections (see §40.69 for procedures). This is the only circumstance in which you may conduct a monitored collection.

(3) No one but the employee may be present in the multistall restroom during the collection, except for the monitor in the event of a monitored collection or the observer in the event of a directly observed collection.

(g) A collection site may be in a medical facility, a mobile facility (*e.g.*, a van), a dedicated collection facility, or any other location meeting the requirements of this section.

[53 FR 47002, Nov. 21, 1988; removed by Amdt. 40-1, 54 FR 49854, Dec. 1, 1989; added by Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§40.43 What steps must operators of collection sites take to protect the security and integrity of urine collections?

(a) Collectors and operators of collection sites must take the steps listed in this section to prevent unauthorized access that could compromise the integrity of collections.

(b) As a collector, you must do the following before each collection to deter tampering with specimens:

(1) Secure any water sources or otherwise make them unavailable to employees (*e.g.*, turn off water inlet, tape handles to prevent opening faucets);

(2) Ensure that the water in the toilet is blue;

(3) Ensure that no soap, disinfectants, cleaning agents, or other possible adulterants are present;

(4) Inspect the site to ensure that no foreign or unauthorized substances are present;

(5) Tape or otherwise secure shut any movable toilet tank top, or put bluing in the tank;

(6) Ensure that undetected access (*e.g.*, through a door not in your view) is not possible;

(7) Secure areas and items (*e.g.*, ledges, trash receptacles, paper towel holders, under-sink areas) that appear suitable for concealing contaminants; and

(8) Recheck items in paragraphs (b)(1) through (7) of this section following each collection to ensure the site's continued integrity.

(c) If the collection site uses a facility normally used for other purposes, like a public rest room or hospital examining room, you must, as a collector, also ensure before the collection that:

(1) Access to collection materials and specimens is effectively restricted; and

(2) The facility is secured against access during the procedure to ensure privacy to the employee and prevent distraction of the collector. Limited-access signs must be posted.

(d) As a collector, you must take the following additional steps to ensure security during the collection process:

(1) To avoid distraction that could compromise security, you are limited to

conducting a collection for only one employee at a time. However, during the time one employee is in the period for drinking fluids in a "shy bladder" situation (see §40.193(b)), you may conduct a collection for another employee.

(2) To the greatest extent you can, keep an employee's collection container within view of both you and the employee between the time the employee has urinated and the specimen is sealed.

(3) Ensure you are the only person in addition to the employee who handles the specimen before it is poured into the bottles and sealed with tamper-evident seals.

(4) In the time between when the employee gives you the specimen and when you seal the specimen, remain within the collection site.

(5) Maintain personal control over each specimen and CCF throughout the collection process.

(e) If you are operating a collection site, you must implement a policy and procedures to prevent unauthorized personnel from entering any part of the site in which urine specimens are collected or stored.

(1) Only employees being tested, collectors and other collection site workers, DERs, employee and employer representatives authorized by the employer (*e.g.*, employer policy, collective bargaining agreement), and DOT agency representatives are authorized persons for purposes of this paragraph (e).

(2) Except for the observer in a directly observed collection or the monitor in the case of a monitored collection, you must not permit anyone to enter the urination facility in which employees provide specimens.

(3) You must ensure that all authorized persons are under the supervision of a collector at all times when permitted into the site.

(4) You or the collector may remove any person who obstructs, interferes with, or causes a delay in the collection process.

(f) If you are operating a collection site, you must minimize the number of persons handling specimens.

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§40.45 What form is used to document a DOT urine collection?

(a) The Federal Drug Testing Custody and Control Form (CCF) must be used to document every urine collection required by the DOT drug testing program. The CCF must be a five-part carbonless manifold form. You may view this form on the Department's web site (http://www.dot.gov/ost/dapc) or the HHS web site (http://www.workplace.samhsa.gov).

(b) As a participant in the DOT drug testing program, you are not permitted to modify or revise the CCF except as follows:

(1) You may include, in the area outside the border of the form, other information needed for billing or other purposes necessary to the collection process.

(2) The CCF must include the names, addresses, telephone numbers and fax numbers of the employer and the MRO, which may be preprinted, typed, or handwritten. The MRO information must include the specific physician's name and address, as opposed to only a generic clinic, health care organization, or company name. This information is required, and it is prohibited for an employer, collector, service agent or any other party to omit it. In addition, a C/TPA's name, address, fax number, and telephone number may be included, but is not required.

(3) As an employer, you may add the name of the DOT agency under whose

authority the test occurred as part of the employer information.

(4) As a collector, you may use a CCF with your name, address, telephone number, and fax number preprinted, but under no circumstances may you sign the form before the collection event.

(c) Under no circumstances may the CCF transmit personal identifying information about an employee (other than a social security number (SSN) or other employee identification (ID) number) to a laboratory.

(d) As an employer, you may use an equivalent foreign-language version of the CCF approved by ODAPC. You may use such a non-English language form only in a situation where both the employee and collector understand and can use the form in that language.

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000 as amended by Amdt. 40-10a, 66 FR 4677, Jan. 31, 2002]

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

(a) No, as an employer, you are prohibited from using the CCF for non-DOT 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-DOT form is a "correctable flaw." As an MRO, to correct the problem you must follow the procedures of §40.205(b)(2).

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§40.49 What materials are used to collect urine specimens?

For each DOT drug test, you must use a collection kit meeting the requirements of Appendix A of this part.

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§40.51 What materials are used to send urine specimens to the laboratory?

(a) Except as provided in paragraph (b) of this section, you must use a shipping container that adequately protects the specimen bottles from shipment damage in the transport of specimens from the collection site to the laboratory.

(b) You are not required to use a shipping container if a laboratory courier hand-delivers the specimens from the collection site to the laboratory.

[Amdt. 40-2, 59 FR 7340, Feb. 15, 1994 as amended by Amdt. 40-5, 60 FR 19675, Apr. 20, 1995; Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§40.53 [Removed]

[Amdt. 40-2, 59 FR 7340, Feb. 15, 1994 as removed by Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§40.55 [Removed]

[Amdt. 40-2, 59 FR 7340, Feb. 15, 1994 as removed by Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§40.57 [Removed]

[Amdt. 40-2, 59 FR 7340, Feb. 15, 1994 as removed by Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§40.59 [Removed]

[Amdt. 40-2, 59 FR 7340, Feb. 15, 1994 as amended by Amdt. 40-3, 59 FR 42996, Aug. 19, 1994, Amdt. 40-5, 60 FR 19675, Apr. 20, 1995 as removed by Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

Subpart E–Urine Specimen Collections

§40.61 What are the preliminary steps in the collection process?

As the collector, you must take the following steps before actually beginning a collection:

(a) When a specific time for an employee's test has been scheduled, or the collection site is at the employee's work site, and the employee does not appear at the collection site at the scheduled time, contact the DER to determine the appropriate interval within which the DER has determined the employee is authorized to arrive. If the employee's arrival is delayed beyond that time, you must notify the DER that the employee has not reported for testing. In a situation where a C/TPA has notified an owner/operator or other individual employee to report for testing and the employee does not appear, the C/TPA must notify the employee that he or she has refused to test (see §40.191(a)(1)).

(b) Ensure that, when the employee enters the collection site, you begin the testing process without undue delay. For example, you must not wait because the employee says he or she is not ready or is unable to urinate or because an authorized employer or employee representative is delayed in arriving.

(1) If the employee is also going to take a DOT alcohol test, you must, to the greatest extent practicable, ensure that the alcohol test is completed before the urine collection process begins.

Example to Paragraph (b)(1): An employee enters the test site for both a drug and an alcohol test. Normally, the collector would wait until the BAT had completed the alcohol test process before beginning the drug test process. However, there are some situations in which an exception to this normal practice would be reasonable. One such situation might be if several people were waiting for the BAT to conduct alcohol tests, but a drug testing collector in the same facility were free. Someone waiting might be able to complete a drug test without unduly delaying his or her alcohol test. Collectors and BATs should work together, however, to ensure that post-accident and reasonable suspicion alcohol tests happen as soon as possible (*e.g.*, by moving the employee to the head of the line for alcohol tests).

(2) If the employee needs medical attention (*e.g.*, an injured employee in an emergency medical facility who is required to have a post-accident test), do not delay this treatment to collect a specimen.

(3) You must not collect, by catheterization or other means, urine from an unconscious employee to conduct a drug test

under this part. Nor may you catheterize a conscious employee. However, you must inform an employee who normally voids through self-catheterization that the employee is required to provide a specimen in that manner.

(4) If, as an employee, you normally void through self-catheterization, and decline to do so, this constitutes a refusal to test.

(c) Require the employee to provide positive identification. You must see a photo ID issued by the employer (other than in the case of an owner-operator or other self-employed individual) or a Federal, state, or local government (*e.g.*, a driver's license). You may not accept faxes or photocopies of identification. Positive identification by an employer representative (not a co-worker or another employee being tested) is also acceptable. If the employee cannot produce positive identification, you must contact a DER to verify the identity of the employee.

(d) If the employee asks, provide your identification to the employee. Your identification must include your name and your employer's name, but does not have to include your picture, address, or telephone number.

(e) Explain the basic collection procedure to the employee, including showing the employee the instructions on the back of the CCF.

(f) Direct the employee to remove outer clothing (*e.g.*, coveralls, jacket, coat, hat) that could be used to conceal items or substances that could be used to tamper with a specimen. You must also direct the employee to leave these garments and any briefcase, purse, or other personal belongings with you or in a mutually agreeable location. You must advise the employee that failure to comply with your directions constitutes a refusal to test.

(1) If the employee asks for a receipt for any belongings left with you, you must provide one.

(2) You must allow the employee to keep his or her wallet.

(3) You must not ask the employee to remove other clothing (*e.g.*, shirts, pants, dresses, underwear), to remove all clothing, or to change into a hospital or examination gown (unless the urine collection is being accomplished simultaneously with a DOT agency-authorized medical examination).

(4) You must direct the employee to empty his or her pockets and display the items in them to ensure that no items are present which could be used to adulterate the specimen. If nothing is there that can be used to adulterate a specimen, the employee can place the items back into his or her pockets. As the employee, you must allow the collector to make this observation.

(5) If, in your duties under paragraph (f)(4) of this section, you find any material that could be used to tamper with a specimen, you must:

(i) Determine if the material appears to be brought to the collection site with the intent to alter the specimen, and, if it is, conduct a directly observed collection using direct observation procedures (see §40.67); or

(ii) Determine if the material appears to be inadvertently brought to the collection site (*e.g.*, eye drops), secure and maintain it until the collection process is completed and conduct a normal (*i.e.*, unobserved) collection.

(g) You must instruct the employee not to list medications that he or she is currently taking on the CCF. (The employee may make notes of medications on the back of the employee copy of the form for his or her own convenience, but these notes must not be transmitted to anyone else.)

[Amdt. 40-2, 59 FR 7340, Feb. 15, 1994; Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§40.63 What steps does the collector take in the collection process before the employee provides a urine specimen?

As the collector, you must take the following steps before the employee provides the urine specimen:

(a) Complete Step 1 of the CCF.

(b) Instruct the employee to wash and dry his or her hands at this time. You must tell the employee not to wash his or her hands again until after delivering the specimen to you. You must not give the employee any further access to water or other materials that could be used to adulterate or dilute a specimen.

(c) Select, or allow the employee to select, an individually wrapped or sealed collection container from collection kit materials. Either you or the employee, with both of you present, must unwrap or break the seal of the collection container. You must not unwrap or break the seal on any specimen bottle at this time. You must not allow the employee to take anything from the collection kit into the room used for urination except the collection container.

(d) Direct the employee to go into the room used for urination, provide a specimen of at least 45 mL, not flush the toilet, and return to you with the specimen as soon as the employee has completed the void.

(1) Except in the case of an observed or a monitored collection (see §§ 40.67 and 40.69), neither you nor anyone else may go into the room with the employee.

(2) As the collector, you may set a reasonable time limit for voiding.

(e) You must pay careful attention to the employee during the entire collection process to note any conduct that clearly indicates an attempt to tamper with a specimen (*e.g.*, substitute urine in plain view or an attempt to bring into the collection site an adulterant or urine substitute). If you detect such conduct, you must require that a collection take place immediately under direct observation (see §40.67) and note the conduct and the fact that the collection was observed in the "Remarks" line of the CCF (Step 2). You must also, as soon as possible, inform the DER and collection site supervisor that a collection took place under direct observation and the reason for doing so.

[Amdt. 40-2, 59 FR 7340, Feb. 15, 1994 as amended by Amdt. 40-3, 59 FR 42996, Aug. 19, 1994, Amdt. 40-5, 60 FR 19675, Apr. 20, 1995; Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§40.65 What does the collector check for when the employee presents a specimen?

As a collector, you must check the following when the employee gives the collection container to you:

(a) *Sufficiency of specimen.* You must check to ensure that the specimen contains at least 45 mL of urine.

(1) If it does not, you must follow "shy bladder" procedures (see §40.193(b)).

(2) When you follow "shy bladder" procedures, you must discard the original specimen, unless another problem (*i.e.*, temperature out of range, signs of tampering) also exists.

(3) You are never permitted to combine urine collected from separate voids to create a specimen.

(4) You must discard any excess urine.

(b) *Temperature*. You must check the temperature of the specimen no later than four minutes after the employee has given you the specimen.

(1) The acceptable temperature range is 32-38° C/90-100° F.

(2) You must determine the temperature of the specimen by reading the temperature strip attached to the collection container.

(3) If the specimen temperature is within the acceptable range, you must mark the "Yes" box on the CCF (Step 2).

(4) If the specimen temperature is outside the acceptable range, you must mark the "No" box and enter in the "Remarks" line (Step 2) your findings about the temperature.

(5) If the specimen temperature is outside the acceptable range, you must immediately conduct a new collection using direct observation procedures (see §40.67).

(6) In a case where a specimen is collected under direct observation because of the temperature being out of range, you must process both the original specimen and the specimen collected using direct observation and send the two sets of specimens to the laboratory. This is true even in a case in which the original specimen has insufficient volume but the temperature is out of range. You must also, as soon as possible, inform the DER and collection site supervisor that a collection took place under direct observation and the reason for doing so.

(7) In a case where the employee refuses to provide another specimen (see §40.191(a)(3)) or refuses to provide another specimen under direct observation (see §40.191(a)(4)), you must notify the DER. As soon as you have notified the DER, you must discard any specimen the employee has provided previously during the collection procedure.

(c) Signs of tampering. You must inspect the specimen for unusual color, presence of foreign objects or material, or other signs of tampering (*e.g.*, if you notice any unusual odor).

(1) If it is apparent from this inspection that the employee has tampered with the specimen (*e.g.*, blue dye in the specimen, excessive foaming when shaken, smell of bleach), you must immediately conduct a new collection using direct observation procedures (see §40.67).

(2) In a case where a specimen is collected under direct observation because of showing signs of tampering, you must process both the original specimen and the specimen collected using direct observation and send the two sets of specimens to the laboratory. This is true even in a case in which the original specimen has insufficient volume but it shows signs of tampering. You must also, as soon as possible, inform the DER and collection site supervisor that a collection took place under direct observation and the reason for doing so.

(3) In a case where the employee refuses to provide another specimen (see §40.191(a)(3)) or refuses to provide a specimen under direct observation (see §40.193(a)(4)), you must notify the DER. As soon as you have notified the DER, you must discard any specimen the employee has provided previously during the collection procedure.

[Amdt. 40-2, 59 FR 7340, Feb. 15, 1994 as amended by Amdt. 40-3, 59 FR 42996, Aug. 19, 1994, Amdt. 40-5, 60 FR 19675, Apr. 20, 1995; Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§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 substituted with a creatinine concentration greater than or equal to 2 mg/dL and less than or equal to 5 mg/dL and the MRO reported the specimen to you as negative and dilute (see §§ 40.145(a)(1) and 40.197).

(b) As an employer, you may 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 (c) 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 under this part for a directly observed collection under paragraphs (c)(2) through (4) 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 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.

(j) 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.

(k) 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).

(l) 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.

[Amdt. 40-2, 59 FR 7340, Feb. 15, 1994 as amended by Amdt. 40-10, 65 FR 79462, Dec. 19, 2000; Amdt. 40-11, 68 FR 31624, May 28, 2003]

§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). 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 procedures at paragraphs (d) and (e) of this section. If you, the collector, are the observer, you too 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.

[Amdt. 40-2, 59 FR 7340, Feb. 15, 1994; as amended by Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§40.71 How does the collector prepare the specimens?

(a) All collections under DOT agency drug testing regulations must be split specimen collections.

(b) As the collector, you must take the following steps, in order, after the employee brings the urine specimen to you. You must take these steps in the presence of the employee.

(1) Check the box on the CCF (Step 2) indicating that this was a split specimen collection.

(2) You, not the employee, must first pour at least 30 mL of urine from the collection container into one specimen bottle, to be used for the primary specimen.

(3) You, not the employee, must then pour at least 15 mL of urine from the collection container into the second specimen bottle to be used for the split specimen.

(4) You, not the employee, must place and secure (*i.e.*, tighten or snap) the lids/caps on the bottles.

(5) You, not the employee, must seal the bottles by placing the tamper-evident bottle seals over the bottle caps/lids and down the sides of the bottles.

(6) You, not the employee, must then write the date on the tamper-evident bottle seals.

(7) You must then ensure that the employee initials the tamper-evident bottle seals for the purpose of certifying that the bottles contain the specimens he or she provided. If the employee fails or refuses to do so, you must note this in the "Remarks" line of the CCF (Step 2) and complete the collection process.

[Amdt. 40-2, 59 FR 7340, Feb. 15, 1994 as amended by Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§40.73 How is the collection process completed?

(a) As the collector, you must do the following things to complete the collection process. You must complete the steps called for in paragraphs (a)(1) through (a)(7) of this section in the employee's presence.

(1) Direct the employee to read and sign the certification statement on Copy 2 (Step 5) of the CCF and provide date of birth, printed name, and day and evening contact telephone numbers. If the employee refuses to sign the CCF or to provide date of birth, printed name, or telephone numbers, you must note this in the "Remarks" line (Step 2) of the CCF, and complete the collection. If the employee refuses to fill out any information, you must, as a minimum, print the employee's name in the appropriate place.

(2) Complete the chain of custody on the CCF (Step 5) by printing your name (note: you may pre-print your name), recording the time and date of the collection, signing the statement, and entering the name of the delivery service transferring the specimen to the laboratory,

(3) Ensure that all copies of the CCF are legible and complete.

(4) Remove Copy 5 of the CCF and give it to the employee.

(5) Place the specimen bottles and Copy 1 of the CCF in the appropriate pouches of the plastic bag.

(6) Secure both pouches of the plastic bag.

(7) Advise the employee that he or she may leave the collection site.

(8) To prepare the sealed plastic bag containing the specimens and CCF for shipment you must:

(i) Place the sealed plastic bag in a shipping container (*e.g.*, standard courier box) designed to minimize the possibility of damage during shipment. (More than one sealed plastic bag can be placed into a single shipping container if you are doing multiple collections.)

(ii) Seal the container as appropriate.

(iii) If a laboratory courier hand-delivers the specimens from the collection site to the laboratory, prepare the sealed plastic bag for shipment as directed by the courier service.

(9) Send Copy 2 of the CCF to the MRO and Copy 4 to the DER. You must fax or otherwise transmit these copies to the MRO and DER within 24 hours or during the next business day. Keep Copy 3 for at least 30 days, unless otherwise specified by applicable DOT agency regulations.

(b) As a collector or collection site, you must ensure that each specimen you collect is shipped to a laboratory as quickly as possible, but in any case within 24 hours or during the next business day.

[Amdt. 40-2, 59 FR 7340, Feb. 15, 1994 as amended by Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§§ 40.75 – 40.77 [Removed]

[Amdt. 40-2, 59 FR 7340, Feb. 15, 1994 as removed by Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§40.79 [Removed]

[Amdt. 40-2, 59 FR 7340, Feb. 15, 1994 as amended by Amdt. 40-3, 59 FR 42996, Aug. 19, 1994 as removed by Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

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 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.

[Amdt. 40-2, 59 FR 7340, Feb. 15, 1994 as amended by Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§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 the laboratory copy of the CCF. You are not authorized to receive other copies of the CCF nor 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 (g) 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 (g) 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 specimen and CCF for the following "correctable flaws":

(1) The specimen temperature was not checked and the "Remarks" line did not contain an entry regarding the temperature being outside of range; and

(2) The collector's signature is omitted on the certification statement on the CCF.

(f) Upon finding that a specimen meets the criteria of paragraph (e) of this section, 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).

(3) If the flaw is not corrected, report the result in accordance with §40.97(a)(3).

(g) 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.

(h) 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.

[Amdt. 40-2, 59 FR 7340, Feb. 15, 1994 as amended by Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§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).

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§40.87 What are the cutoff concentrations for initial and confirmation 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:

Type of drug or metabolite	Initial test	Confirmation test
(1) Marijuana metabolites	50	
(i) Delta-9-tetrahydrocanna-binol- 9-carboxylic acid (THC).		15
(2) Cocaine metabolites (Benzoylecgonine).	300	150
(3) Phencyclidine (PCP)	25	25
(4) Amphetamines	1000	
(i) Amphetamine		500
(ii) Methamphetamine		500 (Specimen must also contain amphetamine at a concentration of greater than or equal to 200 ng/mL.)
(5) Opiate metabolites	2000	
(i) Codeine		2000
(ii) Morphine		2000
(iii) 6-acetylmorphine (6-AM)		10 (Test for 6-AM in the specimen. Conduct this test only when specimen contains morphine at a concentration greater than or equal to 2000 ng/mL.)

(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.

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§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.

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§40.91 What validity tests must laboratories conduct on primary specimens?

As a laboratory, when you conduct validity testing under §40.89, you must conduct it in

accordance with the requirements of this section.

(a) You must test each primary specimen for creatinine. You must also determine its specific gravity if you find that the creatinine concentration is less than 20 mg/dL.

(b) You must measure the pH of each primary specimen.

(c) You must test each primary specimen to determine if it contains substances that may be used to adulterate the specimen. Your tests must have the capability of determining whether any substance identified in current HHS requirements or specimen validity guidance is present in the specimen.

(d) If you suspect the presence of an interfering substance/
adulterant that could make a test result invalid, but you are unable to identify it (*e.g.*, a new adulterant), you must, as the first laboratory, send the specimen to another HHS certified laboratory that has the capability of doing so.

(e) If you identify a substance in a specimen that appears to be an adulterant, but which is not listed in current HHS requirements or guidance, you must report the finding in writing to ODAPC and the Division of Workplace Programs, HHS, within three business days. You must also complete testing of the specimen for drugs, to the extent technically feasible.

(f) You must conserve as much as possible of the specimen for possible future testing.

[Amdt. 40-5, 60 FR 19675, Apr. 20, 1995 as amended by Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§40.93 What criteria do laboratories use to establish that a specimen is dilute or substituted?

(a) As a laboratory you must consider the primary specimen to be dilute if the creatinine concentration is less than 20 mg/dL and the specific gravity is less than 1.003, unless the criteria for a substituted specimen are met.

(b) As a laboratory you must consider the primary specimen to be substituted if the creatinine concentration is less than or equal to 5 mg/dL and the specific gravity is less than or equal to 1.001 or greater than or equal to 1.020.

[Amdt. 40-5, 60 FR 19675, Apr. 20, 1995 as amended by Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§40.95 What criteria do laboratories use to establish that a specimen is adulterated?

(a) As a laboratory, you must consider the primary specimen to be adulterated if you determine that–

(1) A substance that is not expected to be present in human urine is identified in the specimen;

(2) A substance that is expected to be present in human urine is identified at a concentration so high that it is not consistent with human urine; or

(3) The physical characteristics of the specimen are outside the normal expected range for human urine.

(b) In making your determination under paragraph (a) of this section, you must apply the criteria in current HHS requirements or specimen validity guidance.

[Amdt. 40-5, 60 FR 19675, Apr. 20, 1995 as amended by Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§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 tested as one of the following:

(1) Negative;

(2) Negative–dilute;

(3) Rejected for testing, with remark(s);

(4) Positive, with drug(s)/metabolite(s) noted;

(5) Positive, with drug(s)/metabolite(s) noted–dilute;

(6) Adulterated, with remark(s);

(7) Substituted, with quantitative values for creatinine and specific gravity, and remarks; or

(8) Invalid result, 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;

(B) Employer's name (you may include I.D. or account number;

(C) Specimen I.D. number;

(D) Donor's SSN or employee I.D. number, if provided; `

(E) Reason for test, if provided;

(F) Date of the collection;

(G) Date received at the laboratory;

(H) Date certifying scientist released the results;

(I) Results (*e.g.*, positive, adulterated) as listed in paragraph (a) of this section; and

(J) Remarks section, with an explanation of any situation in which a correctable flaw has been corrected.

(ii) The laboratory results report may be released only after review and approval by the certifying scientist and must reflect the same test result information as contained on the CCF signed by the certifying scientist.

(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 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 and adulterated test results to the MRO when the MRO requests you to do so in writing. The MRO's request may be either a general request covering all such results you send to the MRO or a specific case-by-case request.

(2) You must also provide to the MRO quantitative values for creatinine and specific gravity for all substituted test results when the result is above your detection limit. If the result is not above your detection limit, you must report “creatinine not detected” to the MRO. You must make these reports for in all cases of substituted tests, 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.

[Amdt. 40-5, 60 FR 19675, Apr. 20, 1995 as amended by Amdt. 40-10, 65 FR 79462, Dec. 19, 2000; Amdt. 40-11, 68 FR 31624, May 28, 2003]

§40.99 How long does the laboratory retain specimens after testing?

(a) As a laboratory testing the primary specimen, you must retain a specimen that was reported with positive, adulterated, substituted, or invalid results for a minimum of one year.

(b) You must keep such a specimen in secure, long-term, frozen storage in accordance with HHS requirements.

(c) Within the one-year period, the MRO, the employee, the employer, or a DOT agency may request in writing that you retain a specimen for an additional period of time (*e.g.*, for the purpose of preserving evidence for litigation or a safety investigation). If you receive such a request, you must comply with it. If you do not receive such a request, you may discard the specimen at the end of the year.

(d) If you have not sent the split specimen to another laboratory for testing, you must retain the split specimen for an employee's test for the same period of time that you retain the primary specimen and under the same storage conditions.

(e) As the laboratory testing the split specimen, you must meet the requirements of paragraphs (a) through (d) of this section with respect to the split specimen.

[Amdt. 40-5, 60 FR 19675, Apr. 20, 1995 as amended by Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§40.101 What relationship may a laboratory have with an MRO?

(a) As a laboratory, you may not enter into any relationship with an MRO that creates a conflict of interest or the appearance of a conflict of interest with the MRO's responsibilities for the employer. You may not derive any financial benefit by having an employer use a specific MRO.

(b) The following are examples of relationships between laboratories and MROs that the Department regards as creating conflicts of interest, or the appearance of such conflicts. This following list of examples is not intended to be exclusive or exhaustive:

(1) The laboratory employs an MRO who reviews test results produced by the laboratory;

(2) The laboratory has a contract or retainer with the MRO for the review of test results produced by the laboratory;

(3) The laboratory designates which MRO the employer is to use, gives the employer a slate of MROs from which to choose, or recommends certain MROs;

(4) The laboratory gives the employer a discount or other incentive to use a particular MRO;

(5) The laboratory has its place of business co-located with that of an MRO or MRO staff who review test results produced by the laboratory; or

(6) The laboratory permits an MRO, or an MRO's organization, to have a financial interest in the laboratory.

[Amdt. 40-5, 60 FR 19675, Apr. 20, 1995 as amended by Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§40.103 What are the requirements for submitting blind specimens to a laboratory?

(a) As an employer or C/TPA with an aggregate of 2000 or more DOT-covered employees, you must send blind specimens to laboratories you use. If you have an aggregate of fewer than 2000 DOT-covered employees, you are not required to provide blind specimens.

(b) To each laboratory to which you send at least 100 specimens in a year, you must transmit a number of blind specimens equivalent to one percent of the specimens you send to that laboratory, up to a maximum of 50 blind specimens in each quarter (*i.e.*, January-March, April-June, July-September, October-December). As a C/TPA, you must apply this percentage to the total number of DOT-covered employees' specimens you send to the laboratory. Your blind specimen submissions

must be evenly spread throughout the year. The following examples illustrate how this requirement works:

Example 1 to Paragraph (b). You send 2500 specimens to Lab X in Year 1. In this case, you would send 25 blind specimens to Lab X in Year 1. To meet the even distribution requirement, you would send 6 in each of three quarters and 7 in the other.

Example 2 to Paragraph (b). You send 2000 specimens to Lab X and 1000 specimens to Lab Y in Year 1. In this case, you would send 20 blind specimens to Lab X and 10 to Lab Y in Year 1. The even distribution requirement would apply in a similar way to that described in Example 1.

Example 3 to Paragraph (b). Same as Example 2, except that you also send 20 specimens to Lab Z. In this case, you would send blind specimens to Labs X and Y as in Example 2. You would not have to send any blind specimens to Lab Z, because you sent fewer than 100 specimens to Lab Z.

Example 4 to Paragraph (b). You are a C/TPA sending 2000 specimens to Lab X in Year 1. These 2000 specimens represent 200 small employers who have an average of 10 covered employees each. In this case you–not the individual employers–send 20 blind specimens to Lab X in Year 1, again ensuring even distribution. The individual employers you represent are not required to provide any blind specimens on their own.

Example 5 to Paragraph (b). You are a large C/TPA that sends 40,000 specimens to Lab Y in Year 1. One percent of that figure is 400. However, the 50 blind specimen per quarter "cap" means that you need send only 50 blind specimens per quarter, rather than the 100 per quarter you would have to send to meet the one percent rate. Your annual total would be 200, rather than 400, blind specimens.

(c) Approximately 75 percent of the specimens you submit must be blank (*i.e.*, containing no drugs, nor adulterated or substituted). Approximately 15 percent must be positive for one or more of the five drugs involved in DOT tests, and approximately 10 percent must either be adulterated with a substance cited in HHS guidance or substituted (*i.e.*, having specific gravity and creatinine meeting the criteria of §40.93(b)).

(1) The blind specimens that you submit that contain drugs, that are adulterated with a substance cited in HHS guidance, or that are substituted must be validated as to their contents by the supplier using initial and confirmatory tests.

(2) The supplier must provide information regarding the shelf life of the blind specimens.

(3) If the blind specimen is drug positive, the concentration of drug it contains must be between 1.5 and 2 times the initial drug test cutoff concentration.

(4) If the blind specimen is adulterated with nitrite, the concentration of nitrite it contains must be between 1.5 and 2 times the initial validity test cutoff concentration.

(5) If the blind specimen is adulterated by altering pH, the pH must be less than or equal to 2, or greater than or equal to 12.

(6) If the blind specimen is substituted, the creatinine must be less than or equal to 2, and the specific gravity must be 1.000.

(d) You must ensure that each blind specimen is indistinguishable to the laboratory from a normal specimen.

(1) You must submit blind specimens to the laboratory using the same channels (*e.g.*, via a regular collection site) through which employees' specimens are sent to the laboratory.

(2) You must ensure that the collector uses a CCF, places fictional initials on the specimen bottle label/seal, indicates for the MRO on Copy 2 that the specimen is a blind specimen, and discards Copies 4 and 5 (employer and employee copies).

(3) You must ensure that all blind specimens include split specimens.

§40.105 What happens if the laboratory reports a result different from that expected for a blind specimen?

(a) If you are an employer, MRO, or C/TPA who submits a blind specimen, and if the result reported to the MRO is different from the result expected, you must investigate the discrepancy.

(b) If the unexpected result is a false negative, you must provide the laboratory with the expected results (obtained from the supplier of the blind specimen), and direct the laboratory to determine the reason for the discrepancy.

(c) If the unexpected result is a false positive, you must provide the laboratory with the expected results (obtained from the supplier of the blind specimen), and direct the laboratory to determine the reason for the discrepancy. You must also notify ODAPC of the discrepancy by telephone (202-366-3784) or e-mail (addresses are listed on the ODAPC web site, http://www.dot.gov/ost/dapc). ODAPC will notify HHS who will take appropriate action.

[Amdt. 40-5, 60 FR 19675, Apr. 20, 1995 as amended by Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§40.107 Who may inspect laboratories?

As a laboratory, you must permit an inspection, with or without prior notice, by ODAPC, a DOT agency, or a DOT-regulated employer that contracts with the laboratory for drug testing under the DOT drug testing program, or the designee of such an employer.

[Amdt. 40-5, 60 FR 19675, Apr. 20, 1995 as amended by Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§40.109 What documentation must the laboratory keep, and for how long?

(a) As a laboratory, you must retain all records pertaining to each employee urine specimen for a minimum of two years.

(b) As a laboratory, you must also keep for two years employer-specific data required in §40.111.

(c) Within the two-year period, the MRO, the employee, the employer, or a DOT agency may request in writing that you retain the records for an additional period of time (*e.g.*, for the purpose of preserving evidence for litigation or a safety investigation). If you receive such a request, you must comply with it. If you do not receive such a request, you may discard the records at the end of the two-year period.

[Amdt. 40-5, 60 FR 19675, Apr. 20, 1995 as amended by Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§40.111 When and how must a laboratory disclose statistical summaries and other information it maintains?

(a) As a laboratory, you must transmit an aggregate statistical summary, by employer, of the data listed in Appendix B to this part to the employer on a semi-annual basis.

(1) The summary must not reveal the identity of any employee.

(2) In order to avoid sending data from which it is likely that information about an employee's test result can be readily inferred, you must not send a summary if the employer has fewer than five aggregate tests results.

(3) The summary must be sent by January 20 of each year for July 1 through December 31 of the prior year.

(4) The summary must also be sent by July 20 of each year for January 1 through June 30 of the current year.

(b) When the employer requests a summary in response to an inspection, audit, or review by a DOT agency, you must provide it unless the employer had fewer than five aggregate test results. In that case, you must send the employer a report indicating that not enough testing was conducted to warrant a summary. You may transmit the summary or report by hard copy, fax, or other electronic means.

(c) You must also release information to appropriate parties as provided in §§ 40.329 and 40.331.

[Amdt. 40-5, 60 FR 19675, Apr. 20, 1995 as amended by Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§40.113 Where is other information concerning laboratories found in this regulation?

You can find more information concerning laboratories in several sections of this part:

§40.3–Definition.
§40.13–Prohibition on making specimens available for other purposes.
§40.31–Conflicts of interest concerning collectors.
§40.47–Laboratory rejections of test for improper form.
§40.125–Conflicts of interest concerning MROs.
§40.175–Role of first laboratory in split specimen tests.
§40.177–Role of second laboratory in split specimen tests (drugs).
§40.179–Role of second laboratory in split specimen tests (adulterants).
§40.181–Role of second laboratory in split specimen tests (substitution).
§§ 40.183-40.185–Transmission of split specimen test results to MRO.
§§ 40.201-40.205–Role in correcting errors.
§40.329–Release of information to employees.
§40.331–Limits on release of information.
§40.355–Role with respect to other service agents.

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

Subpart G–Medical Review Officers and the Verification Process

§40.121 Who is qualified to act as an MRO?

To be qualified to act as an MRO in the DOT drug testing program, you must meet each of the requirements of this section:

(a) *Credentials.* You must be a licensed physician (Doctor of Medicine or Osteopathy). If you are a licensed physician in any U.S., Canadian, or Mexican jurisdiction and meet the other requirements of this section, you are authorized to perform MRO services with respect to all covered employees, wherever they are located. For example, if you are licensed as an M.D. in one state or province in the U.S., Canada, or Mexico, you are not limited to performing MRO functions in that state or province, and you may perform MRO functions for employees in other states or provinces without becoming licensed to practice medicine in the other jurisdictions.

(b) *Basic knowledge.* You must be knowledgeable in the following areas:

(1) You must be knowledgeable about and have clinical experience in controlled substances abuse disorders, including detailed knowledge of alternative medical explanations for laboratory confirmed drug test results.

(2) You must be knowledgeable about issues relating to adulterated and substituted specimens as well as the possible medical causes of specimens having an invalid result.

(3) You must be knowledgeable about this part, the DOT MRO Guidelines, and the DOT agency regulations applicable to the employers for whom you evaluate drug test results, and you must keep current on any changes to these materials. The DOT MRO Guidelines document is 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) Collection procedures for urine specimens;

(ii) Chain of custody, reporting, and recordkeeping;

(iii) Interpretation of drug and validity tests results;

(iv) The role and responsibilities of the MRO in the DOT drug testing program;

(v) The interaction with other participants in the program (*e.g.*, DERs, SAPs); and

(vi) Provisions of this part and DOT agency rules applying to employers for whom you review test results, including changes and updates to this part and DOT agency rules, guidance, interpretations, and policies affecting the performance of MRO functions, as well as issues that MROs confront in carrying out their duties under this part and DOT agency rules.

(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 MRO certification board or subspecialty board for medical practitioners in the field of medical review of DOT-mandated drug tests. 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 an MRO before August 1, 2001, and have already met the qualification training requirement, you do not have to meet it again.

(ii) If you became an MRO before August 1, 2001, but have not yet met the qualification training requirement, you must do so no later than January 31, 2003.

(iii) If you become an MRO on or after August 1, 2001, you must meet the qualification training requirement before you begin to perform MRO 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.*, Continuing Education Medical Units) relevant to performing MRO functions.

(1) This continuing education must include material concerning new technologies, interpretations, recent guidance, rule changes, and other information about developments in MRO 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 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 negotiating to use your services.

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§40.123 What are the MRO's responsibilities in the DOT drug testing program?

As an MRO, you have the following basic responsibilities:

(a) Acting as an independent and impartial "gatekeeper" and advocate for the accuracy and integrity of the drug testing process.

(b) Providing a quality assurance review of the drug testing process for the specimens under your purview. This includes, but is not limited to:

(1) Ensuring the review of the CCF on all specimen collections for the purposes of determining whether there is a problem that may cause a test to be cancelled (see §§ 40.199-40.203). As an MRO, you are not required to review laboratory internal chain of custody documentation. No one is permitted to cancel a test because you have not reviewed this documentation;

(2) Providing feedback to employers, collection sites and laboratories regarding performance issues where necessary; and

(3) Reporting to and consulting with the ODAPC or a relevant DOT agency when you wish DOT assistance in resolving any program issue. As an employer or service agent, you are

prohibited from limiting or attempting to limit the MRO's access to DOT for this purpose and from retaliating in any way against an MRO for discussing drug testing issues with DOT.

(c) You must determine whether there is a legitimate medical explanation for confirmed positive, adulterated, substituted, and invalid drug tests results from the laboratory.

(d) While you provide medical review of employees' test results, this part does not deem that you have established a doctor-patient relationship with the employees whose tests you review.

(e) You must act to investigate and correct problems where possible and notify appropriate parties (*e.g.*, HHS, DOT, employers, service agents) where assistance is needed, (*e.g.*, cancelled or problematic tests, incorrect results, problems with blind specimens).

(f) You must ensure the timely flow of test results and other information to employers.

(g) You must protect the confidentiality of the drug testing information.

(h) You must perform all your functions in compliance with this part and other DOT agency regulations.

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§40.125 What relationship may an MRO have with a laboratory?

As an MRO, you may not enter into any relationship with an employer's laboratory that creates a conflict of interest or the appearance of a conflict of interest with your responsibilities to that employer. You may not derive any financial benefit by having an employer use a specific laboratory. For examples of relationships between laboratories and MROs that the Department views as creating a conflict of interest or the appearance of such a conflict, see §40.101(b).

§40.127 What are the MRO's functions in reviewing negative test results?

As the MRO, you must do the following with respect to negative drug test results you receive from a laboratory, prior to verifying the result and releasing it to the DER:

(a) Review Copy 2 of the CCF to determine if there are any fatal or correctable errors that may require you to initiate corrective action or to cancel the test (see §§ 40.199 and 40.203).

(b) Review the negative laboratory test result and ensure that it is consistent with the information contained on the CCF.

(c) Before you report a negative test result, you must have in your possession the following documents:

(1) Copy 2 of the CCF, a legible copy of it, or any other CCF copy containing the employee's signature; and

(2) A legible copy (fax, photocopy, image) of Copy 1 of the CCF or the electronic laboratory results report that conveys the negative laboratory test result.

(d) If the copy of the documentation provided to you by the collector or laboratory appears unclear, you must request that the collector or laboratory send you a legible copy.

(e) On Copy 2 of the CCF, place a check mark in the "Negative" box (Step 6), provide your name, and sign, initial, or stamp and date the verification statement.

(f) Report the result in a confidential manner (see §§ 40.163-40.167).

(g) Staff under your direct, personal supervision may the administrative functions of this section for you, but only you can cancel a test.

(1) On specimen results that are reviewed by your staff, you are responsible for assuring the quality of their work.

(2) You are required to personally review at least 5 percent of all CCFs reviewed by your staff on a quarterly basis, including all results that required a corrective action. However, you need not review more than 500 negative results in any quarter.

(3) Your review must, as a minimum, include the CCF, negative laboratory test result, any accompanying corrective documents, and the report sent to the employer.

You must correct any errors that you discover. You must take action as necessary to ensure compliance by your staff with this part and document your corrective action. You must attest to the quality assurance review by initialing the CCFs that you review.

(4) You must make these CCFs easily identifiable and retrievable by you for review by DOT agencies.

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§40.129 What are the MRO's functions in reviewing laboratory confirmed positive, adulterated, substituted, or invalid drug test results?

(a) As the MRO, you must do the following with respect to confirmed positive, adulterated, substituted, or invalid drug tests you receive from a laboratory, before you verify the result and release it to the DER:

(1) Review Copy 2 of the CCF to determine if there are any fatal or correctable errors that may require you to cancel the test (see §§ 40.199 and 40.203). Staff under your direct, personal supervision may conduct this administrative review for you, but only you may verify or cancel a test.

(2) Review Copy 1 of the CCF and ensure that it is consistent with the information contained on Copy 2, that the test result is legible, and that the certifying scientist signed the form. You are not required to review any other documentation generated by the laboratory during their analysis or handling of the specimen (*e.g.*, the laboratory internal chain of custody).

(3) If the copy of the documentation provided to you by the collector or laboratory appears unclear, you must request that the collector or laboratory send you a legible copy.

(4) Except in the circumstances spelled out in §40.133 , conduct a verification interview. This interview must include direct contact in person or by telephone between you and the employee. You may initiate the verification process based on the laboratory results report.

(5) Verify the test result as either negative, positive, test cancelled, or refusal to test because of adulteration or substitution, consistent with the requirements of §§ 40.135-40.145 and 40.159 .

(b) Before you report a verified negative, positive, test cancelled, refusal to test because of adulteration or substitution, you must have in your possession the following documents:

(1) Copy 2 of the CCF, a legible copy of it, or any other CCF copy containing the employee's signature; and

(2) A legible copy (fax, photocopy, image) of Copy 1 of the CCF, containing the certifying scientist's signature.

(c) With respect to verified positive test results, place a check mark in the “Positive” box (Step 6) on Copy 2 of the CCF, indicate the drug(s)/ metabolite(s) detected on the “Remarks” line, sign and date the verification statement.

(d) Report the result in a confidential manner (see §§ 40.163-40.167).

(e) With respect to adulteration or substitution test results, check the “refusal to test because:” box (Step 6) on Copy 2 of the CCF, check the “Adulterated” or “Substituted” box, as appropriate, make appropriate annotation in the “Remarks” line, sign and date the verification statement.

(f) As the MRO, your actions concerning reporting confirmed positive, adulterated, or substituted results to the employer before you have completed the verification process are also governed by the stand-down provisions of §40.21 .

(1) If an employer has a stand-down policy that meets the requirements of §40.21 , you may report to the DER that you have received an employee's laboratory confirmed positive, adulterated, or substituted test result, consistent with the terms of the waiver the employer

received. You must not provide any further details about the test result (*e.g.*, the name of the drug involved).

(2) If the employer does not have a stand-down policy that meets the requirements of §40.21 , you must not inform the employer that you have received an employee's laboratory confirmed positive, adulterated, or substituted test result until you verify the test result. For example, as an MRO employed directly by a company, you must not tell anyone on the company's staff or management that you have received an employee's laboratory confirmed test result.

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§40.131 How does the MRO or DER notify an employee of the verification process after a confirmed positive, adulterated, substituted, or invalid test result?

(a) When, as the MRO, you receive a confirmed positive, adulterated, substituted with a creatinine concentration of less than 2 mg/dL, 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 must contact the MRO within the next 72 hours and tell the employee the consequences of failing to do so (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.

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000 as amended by Amdt. 40-11, 68 FR 31624, May 28, 2003]

§40.133 Under what circumstances may the MRO verify a test as positive, or as a refusal to test because of adulteration or substitution, without interviewing the employee?

(a) As the MRO, you normally may verify a confirmed positive test (for any drug or drug metabolite, including opiates), or as a refusal to test because of adulteration or substitution, only after interviewing the employee as provided in §§ 40.135-40.145 . However, there are three circumstances in which you may verify such a result without an interview:

(1) You may verify a test result as a positive or refusal to test, as applicable, if the employee expressly declines the opportunity to discuss the test with you. You must maintain complete documentation of this occurrence, including notation of informing, or attempting to inform, the employee of the consequences of not exercising the option to speak with the you.

(2) You may verify a test result as a positive or refusal to test, as applicable, if the DER has successfully made and documented a contact with the employee and instructed the employee to contact you and more than 72 hours have passed since the time the DER contacted the employee.

(3) You may verify a test result as a positive or refusal to test, as applicable, if neither you nor the DER, after making and documenting all reasonable efforts, has been able to contact the employee within ten days of the date on which the MRO receives the confirmed test result from the laboratory.

(b) As the MRO, when you verify a test result as a positive or refusal to test under this section, you must document the date, time and reason, following the instructions in §40.163 .

(c) As the MRO, after you have verified a test result as a positive or refusal to test under this section and reported the result to the DER, you must allow the employee to present information to you within 60 days of the verification documenting that serious illness, injury, or other circumstances unavoidably precluded contact with the MRO and/ or DER in the times provided. On the basis of such information, you may reopen the verification, allowing the employee to present information concerning whether there is a legitimate medical explanation for the confirmed test result.

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§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, before informing any third party about any medication the employee is using pursuant to a legally valid prescription under the Controlled Substances Act, you will, if the employee consents, contact the prescribing physician 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.

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§40.137 On what basis does the MRO verify test results involving marijuana, cocaine, amphetamines, or PCP?

(a) As the MRO, you must verify a confirmed positive test result for marijuana, cocaine, amphetamines, and/or PCP unless the employee presents a legitimate medical explanation for the presence of the drug(s)/metabolite(s) in his or her system.

(b) You must offer the employee an opportunity to present a legitimate medical explanation in all cases.

(c) The employee has the burden of proof that a legitimate medical explanation exists. The employee must present information meeting this burden at the time of the verification interview. As the MRO, you have discretion to extend the time available to the employee for this purpose for up to five days before verifying the test result, if you determine that there is a reasonable basis to believe that the employee will be able to produce relevant evidence concerning a legitimate medical explanation within that time.

(d) If you determine that there is a legitimate medical explanation, you must verify the test result as negative. Otherwise, you must verify the test result as positive.

(e) In determining whether a legitimate medical explanation exists, you may consider the employee's use of a medication from a foreign country. You must exercise your professional judgment consistently with the following principles:

(1) There can be a legitimate medical explanation only with respect to a substance that is obtained legally in a foreign country.

(2) There can be a legitimate medical explanation only with respect to a substance that has a legitimate medical use. Use of a drug of abuse (*e.g.*, heroin, PCP, marijuana) or any other substance (see §40.151(f) and (g)) that cannot be viewed as having a legitimate medical use can never be the basis for a legitimate medical explanation, even if the substance is obtained legally in a foreign country.

(3) Use of the substance can form the basis of a legitimate medical explanation only if it is used consistently with its proper and intended medical purpose.

(4) Even if you find that there is a legitimate medical explanation under this paragraph (e) and verify a test negative, you may have a responsibility to raise fitness-for-duty considerations with the employer (see §40.327).

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§40.139 On what basis does the MRO verify test results involving opiates?

As the MRO, you must proceed as follows when you receive a laboratory confirmed positive opiate result:

(a) If the laboratory detects the presence of 6-acetylmorphine (6-AM) in the specimen, you must verify the test result positive.

(b) In the absence of 6-AM, if the laboratory detects the presence of either morphine or codeine at 15,000 ng/mL or above, you must verify the test result positive unless the employee presents a legitimate medical explanation for the presence of the drug or drug metabolite in his or her system, as in the case of other drugs (see §40.137). Consumption of food products (*e.g.*, poppy seeds) must not be considered a legitimate medical explanation for the employee having morphine or codeine at these concentrations.

(c) For all other opiate positive results, you must verify a confirmed positive test result for opiates only if you determine that there is clinical evidence, in addition to the urine test, of unauthorized use of any opium, opiate, or opium derivative (*i.e.*, morphine, heroin, or codeine).

(1) As an MRO, it is your responsibility to use your best professional and ethical judgement and discretion to determine whether there is clinical evidence of unauthorized use of opiates. Examples of information that you may consider in making this judgement include, but are not limited to, the following:

(i) Recent needle tracks;

(ii) Behavioral and psychological signs of acute opiate intoxication or withdrawal;

(iii) Clinical history of unauthorized use recent enough to have produced the laboratory test result;

(iv) Use of a medication from a foreign country. See §40.137(e) for guidance on how to make this determination.

(2) In order to establish the clinical evidence referenced in paragraphs (c)(1)(i) and (ii) of this section, personal observation of the employee is essential.

(i) Therefore, you, as the MRO, must conduct, or cause another physician to conduct, a face-to-face examination of the employee.

(ii) No face-to-face examination is needed in establishing the clinical evidence referenced in paragraph (c)(1)(iii) or (iv) of this section.

(3) To be the basis of a verified positive result for opiates, the clinical evidence you find must concern a drug that the laboratory found in the specimen. (For example, if the test confirmed the presence of codeine, and the employee admits to unauthorized use of hydrocodone, you do not have grounds for verifying the test positive. The admission must be for the substance that was found).

(4) As the MRO, you have the burden of establishing that there is clinical evidence of unauthorized use of opiates referenced in this paragraph (c). If you cannot make this determination (*e.g.*, there is not sufficient clinical evidence or history), you must verify the test as negative. The employee does not need to show you that a legitimate medical explanation exists if no clinical evidence is established.

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§40.141 How does the MRO obtain information for the verification decision?

As the MRO, you must do the following as you make the determinations needed for a verification decision:

(a) You must conduct a medical interview. You must review the employee's medical history and any other relevant biomedical factors presented to you by the employee. You may direct the employee to undergo further medical evaluation by you or another physician.

(b) If the employee asserts that the presence of a drug or drug metabolite in his or her specimen results from taking prescription medication, you must review and take all reasonable and necessary steps to verify the authenticity of all medical records the employee provides. You may contact the employee's physician or other relevant medical personnel for further information.

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§40.143 [Reserved]

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§40.145 On what basis does the MRO verify test results involving adulteration or substitution?

(a) As an MRO, when you receive a laboratory report that a specimen is adulterated or substituted, you must treat that report in the same way you treat the laboratory's report of a confirmed positive test for a drug or drug metabolite, unless the creatinine concentration for a substituted specimen was reported by the laboratory to be equal to or more than 2 mg/dL.

(1) If the laboratory has reported the creatinine concentration for a substituted specimen as equal to or more than 2 mg/dL, you must report the specimen to the DER as being dilute, as provided in §40.155 of this part. Notwithstanding any other provision of this part, you must also instruct the DER that a second collection under direct observation must take place immediately.

(2) If the laboratory has reported the creatinine concentration for a substituted specimen as less than 2 mg/dL or "creatinine not detected," you must follow the procedures set forth in paragraphs (b) through (h) of this section.

(b) You must follow the same procedures used for verification of a confirmed positive test for a drug or drug metabolite (see §§ 40.129-40.135, 40.141, 40.151), except as otherwise provided in this section.

(c) In the verification interview, you must explain the laboratory findings to the employee and address technical questions or issues the employee may raise.

(d) You must offer the employee the opportunity to present a legitimate medical explanation for the laboratory findings with respect to presence of the adulterant in, or the creatinine and specific gravity findings for, the specimen.

(e) The employee has the burden of proof that there is a legitimate medical explanation.

(1) To meet this burden in the case of an adulterated specimen, the employee must demonstrate that the adulterant found by the laboratory entered the specimen through physiological means.

(2) To meet this burden in the case of a substituted specimen, the employee must demonstrate that he or she did produce or could have produced urine, through physiological means, meeting criteria for creatinine of less than 2 mg/dL and for specific gravity of less than or equal to 1.001 or greater than or equal to 1.020.

(3) The employee must present information meeting this burden at the time of the verification interview. As the MRO, you have discretion to extend the time available to the employee for this purpose for up to five days before verifying the specimen, if you determine that there is a reasonable basis to believe that the employee will be able to produce relevant

evidence supporting a legitimate medical explanation within that time.

(f) As the MRO or the employer, you are not responsible for arranging, conducting, or paying for any studies, examinations or analyses to determine whether a legitimate medical explanation exists.

(g) As the MRO, you must exercise your best professional judgment in deciding whether the employee has established a legitimate medical explanation.

(1) If you determine that the employee's explanation does not present a reasonable basis for concluding that there may be a legitimate medical explanation, you must report the test to the DER as a verified refusal to test because of adulteration or substitution, as applicable.

(2) If you believe that the employee's explanation may present a reasonable basis for concluding that there is a legitimate medical explanation, you must direct the employee to obtain, within the five-day period set forth in paragraph (e)(3) of this section, a further medical evaluation. This evaluation must be performed by a licensed physician (the "referral physician"), acceptable to you, with expertise in the medical issues raised by the employee's explanation. (The MRO may perform this evaluation if the MRO has appropriate expertise.)

(i) As the MRO or employer, you are not responsible for finding or paying a referral physician. However, on request of the employee, you must provide reasonable assistance to the employee's efforts to find such a physician. The final choice of the referral physician is the employee's, as long as the physician is acceptable to you.

(ii) As the MRO, you must consult with the referral physician, providing guidance to him or her concerning his or her responsibilities under this section. As part of this consultation, you must provide the following information to the referral physician:

(A) That the employee was required to take a DOT drug test, but the laboratory reported that the specimen was adulterated or substituted, which is treated as a refusal to test;

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

(C) That the referral physician must agree to follow the requirements of paragraphs (g)(3) through (g)(4) of this section; and

(D) That the referral physician must provide you with a signed statement of his or her recommendations.

(3) As the referral physician, you must evaluate the employee and consider any evidence the employee presents concerning the employee's medical explanation. You may conduct additional tests to determine whether there is a legitimate medical explanation. Any additional urine tests must be performed in an HHS-certified laboratory.

(4) As the referral physician, you must then make a written recommendation to the MRO about whether the MRO should determine that there is a legitimate medical explanation. As the MRO, you must seriously consider and assess the referral physician's recommendation in deciding whether there is a legitimate medical explanation.

(5) As the MRO, if you determine that there is a legitimate medical explanation, you must cancel the test and inform ODAPC in writing of the determination and the basis for it (*e.g.*, referral physician's findings, evidence produced by the employee).

(6) As the MRO, if you determine that there is not a legitimate medical explanation, you must report the test to the DER as a verified refusal to test because of adulteration or substitution.

(h) The following are examples of types of evidence an employee could present to support an assertion of a legitimate medical explanation for a substituted result.

(1) Medically valid evidence demonstrating that the employee is capable of physiologically producing urine meeting the creatinine and specific gravity criteria of §40.93(b) .

(i) To be regarded as medically valid, the evidence must have been gathered using appropriate methodology and controls to ensure its accuracy and reliability.

(ii) Assertion by the employee that his or her personal characteristics (*e.g.*, with respect to race, gender, weight, diet, working conditions) are responsible for the substituted result does not, in itself, constitute a legitimate medical explanation. To make a case that there is a legitimate medical explanation, the employee must present evidence showing that the cited personal characteristics actually result in the physiological production of urine meeting the creatinine and specific gravity criteria of §40.93(b) .

(2) Information from a medical evaluation under paragraph (g) of this section that the individual has a medical condition that has been demonstrated to cause the employee to physiologically produce urine meeting the creatinine and specific gravity criteria of §40.93(b) .

(i) A finding or diagnosis by the physician that an employee has a medical condition, in itself, does not constitute a legitimate medical explanation.

(ii) To establish there is a legitimate medical explanation, the employee must demonstrate that the cited medical condition actually results in the physiological production of urine meeting the creatinine and specific gravity criteria of §40.93(b) .

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000 as amended by Amdt. 40-11, 68 FR 31624, May 28, 2003]

§40.147 [Reserved]

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§40.149 May the MRO change a verified positive drug test result or refusal to test?

(a) As the MRO, you may change a verified positive or refusal to test drug test result only in the following situations:

(1) When you have reopened a verification that was done without an interview with an employee (see §40.133(c)).

(2) If you receive information, not available to you at the time of the original verification, demonstrating that the laboratory made an error in identifying (*e.g.*, a paperwork mistake) or testing (*e.g.*, a false positive or negative) the employee's primary or split specimen. For example, suppose the laboratory originally reported a positive test result for Employee X and a negative result for Employee Y. You verified the test results as reported to you. Then the laboratory notifies you that it mixed up the two test results, and X was really negative and Y was really positive. You would change X's test result from positive to negative and contact Y to conduct a verification interview.

(3) If, within 60 days of the original verification decision–

(i) You receive information that could not reasonably have been provided to you at the time of the decision demonstrating that there is a legitimate medical explanation for the presence of drug(s)/ metabolite(s) in the employee's specimen; or

(ii) You receive credible new or additional evidence that a legitimate medical explanation for an adulterated or substituted result exists.

Example to Paragraph (a)(3): If the employee's physician provides you a valid prescription that he or she failed to find at the time of the original verification, you may change the test result from positive to negative if you conclude that the prescription provides a legitimate medical explanation for the drug(s)/ metabolite(s) in the employee's specimen.

(4) If you receive the information in paragraph (a)(3) of this section after the 60-day period, you must consult with ODAPC prior to changing the result.

(5) When you have made an administrative error and reported an incorrect result.

(b) If you change the result, you must immediately notify the DER in writing, as provided in §§ 40.163-40.165.

(c) You are the only person permitted to change a verified test result.

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§40.151 What are MROs prohibited from doing as part of the verification process?

As an MRO, you are prohibited from doing the following as part of the verification process:

(a) You must not consider any evidence from tests of urine samples or other body fluids or tissues (*e.g.*, blood or hair samples) that are not collected or tested in accordance with this part. For example, if an employee tells you he went to his own physician, provided a urine specimen, sent it to a laboratory, and received a negative test result or a DNA test result questioning the identity of his DOT specimen, you are required to ignore this test result.

(b) In reviewing the CCF, you must not consider evidence extrinsic to the CCF in determining whether the test is valid. For example, you must review only what is on the face of the CCF for this purpose, not assertions by the employee that the CCF does not accurately reflect what happened at the collection site.

(c) It is not your function to determine whether the employer should have directed that a test occur. For example, if an employee tells you that the employer misidentified her as the subject of a random test, or directed her to take a reasonable suspicion or post-accident test without proper grounds under a DOT agency drug or alcohol regulation, you must inform the employee that you cannot play a role in deciding these issues.

(d) It is not your function to consider explanations of confirmed positive, adulterated, or substituted test results that would not, even if true, constitute a legitimate medical explanation. For example, an employee may tell you that someone slipped amphetamines into her drink at a party, that she unknowingly ingested a marijuana brownie, or that she traveled in a closed car with several people smoking crack. MROs are unlikely to be able to verify the facts of such passive or unknowing ingestion stories. Even if true, such stories do not present a legitimate medical explanation. Consequently, you must not declare a test as negative based on an explanation of this kind.

(e) You must not verify a test negative based on information that a physician recommended that the employee use a drug listed in Schedule I of the Controlled Substances Act. (*e.g.*, under a state law that purports to authorize such recommendations, such as the "medical marijuana" laws that some states have adopted).

(f) You must not accept an assertion of consumption or other use of a hemp or other non-prescription marijuana-related product as a basis for verifying a marijuana test negative. You also must not accept such an explanation related to consumption of coca teas as a basis for verifying a cocaine test result as negative. Consuming or using such a product is not a legitimate medical explanation.

(g) You must not accept an assertion that there is a legitimate medical explanation for the presence of PCP or 6-AM in a specimen. There are no legitimate medical explanations for the presence of these substances.

(h) You must not accept, as a legitimate medical explanation for an adulterated specimen, an assertion that soap, bleach, or glutaraldehyde entered a specimen through physiological means. There are no physiological means through which these substances can enter a specimen.

(i) You must not accept, as a legitimate medical explanation for a substituted specimen, an assertion that an employee can produce urine with no detectable creatinine. There are no physiological means through which a person can produce a urine specimen having this characteristic.

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§40.153 How does the MRO notify employees of their right to a test of the split specimen?

(a) As the MRO, when you have verified a drug test as positive for a drug or drug metabolite, or as a refusal to test because of adulteration or substitution, you must notify the employee of his or her right to have the split specimen tested. You must also notify the employee of the procedures for requesting a test of the split specimen.

(b) You must inform the employee that he or she has 72 hours from the time you provide this notification to him or her to request a test of the split specimen.

(c) You must tell the employee how to contact you to make this request. You must provide telephone numbers or other information that will allow the employee to make this request. As the MRO, you must have the ability to receive the employee's calls at all times during the 72 hour period (*e.g.*, by use of an answering machine with a "time stamp" feature when there is no one in your office to answer the phone).

(d) You must tell the employee that if he or she makes this request within 72 hours, the employer must ensure that the test takes place, and that the employee is not required to pay for the test from his or her own funds before the test takes place. You must also tell the employee that the employer may seek reimbursement for the cost of the test (see §40.173).

(e) You must tell the employee that additional tests of the specimen *e.g.*, DNA tests) are not authorized.

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§40.155 What does the MRO do when a negative or positive test result is also dilute?

(a) When the laboratory reports that a specimen is dilute or reports that a specimen is substituted with a creatinine quantitation of greater than or equal to 2 mg/dL, you must, as the MRO, report to the DER that the specimen, in addition to being negative or positive, is dilute.

(b) You must check the "dilute" box (Step 6) on Copy 2 of the CCF.

(c) You may only report a dilute test result when you are in possession of a legible copy of Copy 1 of the CCF. In addition, you must have Copy 2 of the CCF, a legible copy of it, or any other copy of the CCF containing the employee's signature.

(d) When you report a dilute specimen to the DER, you must explain to the DER the employer's obligations and choices under §40.197.

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000 as amended by Amdt. 40-11, 68 FR 31624, May 28, 2003]

§40.157 [Reserved]

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§40.159 What does the MRO do when a drug test result is invalid?

(a) As the MRO, when the laboratory reports that the test result is an invalid result, you must do the following:

(1) Discuss the laboratory results with a certifying scientist to obtain more specific information.

(2) Contact the employee and inform the employee that the specimen was invalid or contained an unexplained interfering substance. In contacting the employee, use the procedures set forth in §40.131.

(3) After explaining the limits of disclosure (see §§ 40.135(d) and 40.327), you should inquire as to medications the employee may

have taken that may interfere with some immunoassay tests.

(4) If the employee gives an explanation that is acceptable, you must:

(i) Place a check mark in the "Test Cancelled" box (Step 6) on Copy 2 of the CCF and enter "Invalid Result" and "direct observation collection not required" on the "Remarks" line.

(ii) Report to the DER that the test is cancelled, the reason for cancellation, and that no further action is required unless a negative test result is required (*i.e.*, pre-employment, return-to-duty, or follow-up tests).

(5) If the employee is unable to provide an explanation and/or a valid prescription for a medication that interfered with the immunoassay test but denies having adulterated the specimen, you must:

(i) Place a check mark in the "Test Cancelled" box (Step 6) on Copy 2 of the CCF and enter "Invalid Result" and "direct observation collection required" on the "Remarks" line.

(ii) Report to the DER that the test is cancelled, the reason for cancellation, and that a second collection must take place immediately under direct observation.

(iii) Instruct the employer to ensure that the employee has the minimum possible advance notice that he or she must go to the collection site.

(b) You may only report an invalid test result when you are in possession of a legible copy of Copy 1 of the CCF. In addition, you must have Copy 2 of the CCF, a legible copy of it, or any other copy of the CCF containing the employee's signature.

(c) If the employee admits to having adulterated or substituted the specimen, you must, on the same day, write and sign your own statement of what the employee told you. You must then report a refusal to test in accordance with §40.163 .

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§40.161 What does the MRO do when a drug test specimen is rejected for testing?

As the MRO, when the laboratory reports that the specimen is rejected for testing (*e.g.*, because of a fatal or uncorrected flaw), you must do the following:

(a) Place a check mark in the "Test Cancelled" box (Step 6) on Copy 2 of the CCF and enter the reason on the "Remarks" line.

(b) Report to the DER that the test is cancelled and the reason for cancellation, and that no further action is required unless a negative test is required (*e.g.*, in the case of a pre-employment, return-to-duty, or follow-up test).

(c) You may only report a test cancelled because of a rejected for testing test result when you are in possession of a legible copy of Copy 1 of the CCF. In addition, you must have Copy 2 of the CCF, a legible copy of it, or any other copy of the CCF containing the employee's signature.

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§40.163 How does the MRO report drug test results?

(a) As the MRO, it is your responsibility to report the drug test results to the employer in writing.

(1) You or a staff member may rubber stamp a report of negative results. If you use a rubber stamp, you or your staff must also initial the stamp to identify who affixed the stamp to the report.

(2) You, as the MRO, must sign reports of all other results.

(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 as indicated on the CCF (*e.g.*, random, post-accident);

(4) Date of the collection;

(5) Result of the test (*i.e.*, positive, negative, dilute, refusal to test, test cancelled) and the date the result was verified by the MRO;

(6) For verified positive tests, the drug(s)/metabolite(s) for which the test was positive;

(7) For cancelled tests, the reason for cancellation; and

(8) 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) 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.

(e) You must not use Copy 1 of the CCF to report drug test results.

(f) 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)).

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§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.

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§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 written report of verified test to the DER so that the DER receives them within two days of verification by the MRO.

(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.

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§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.

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

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 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.

(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.

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§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.

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§40.175 What steps does the first laboratory take with a split specimen?

(a) As the laboratory at which the primary and split specimen first arrive, you must check to see whether the split specimen is available for testing.

(b) If the split specimen is unavailable or appears insufficient, you must then do the following:

(1) Continue the testing process for the primary specimen as you would normally. Report the results for the primary specimen without providing the MRO information regarding the unavailable split specimen.

(2) Upon receiving a letter from the MRO instructing you to forward the split specimen to another laboratory for testing, report to the MRO that the split specimen is unavailable for testing. Provide as much information as you can about the cause of the unavailability.

(c) As the laboratory that tested the primary specimen, you are not authorized to open the split specimen under any circumstances (except when the split specimen is redesignated as provided in §40.83).

(d) When you receive written notice from the MRO instructing you to send the split specimen to another HHS-certified laboratory, you must forward the following items to the second laboratory:

(1) The split specimen in its original specimen bottle, with the seal intact;

(2) A copy of the MRO's written request; and

(3) A copy of Copy 1 of the CCF, which identifies the drug(s)/metabolite(s) or the validity criteria to be tested for.

(e) You must not send to the second laboratory any information about the identity of the employee. Inadvertent disclosure does not, however, cause a fatal flaw.

(f) This subpart does not prescribe who gets to decide which HHS-certified laboratory is used to test the split specimen. That decision is left to the parties involved.

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§40.177 What does the second laboratory do with the split specimen when it is tested to reconfirm the presence of a drug or drug metabolite?

(a) As the laboratory testing the split specimen, you must test the split specimen for the drug(s)/drug metabolite(s) detected in the primary specimen.

(b) You must conduct this test without regard to the cutoff concentrations of §40.87 .

(c) If the test fails to reconfirm the presence of the drug(s)/drug metabolite(s) that were reported positive in the primary specimen, you must conduct validity tests in an attempt to determine the reason for being unable to reconfirm the presence of the drug(s)/metabolite(s). You should conduct the same validity tests as you would conduct on a primary specimen set forth in §40.91 .

(d) In addition, if the test fails to reconfirm the presence of the drugs/drugs metabolites or validity criteria that were reported in the primary specimen, you may transmit the specimen or an aliquot of it to another HHS-certified laboratory that will conduct another reconfirmation test.

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§40.179 What does the second laboratory do with the split specimen when it is tested to reconfirm an adulterated test result?

As the laboratory testing the split specimen, you must test the split specimen for the adulterant detected in the primary specimen, using the criteria of §40.95 just as you would do for a primary specimen. The result of the primary specimen is reconfirmed if the split specimen meets these criteria.

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§40.181 What does the second laboratory do with the split specimen when it is tested to reconfirm a substituted test result?

As the laboratory testing the split specimen, you must test the split specimen using the criteria of §40.93(b), just as you would do for a primary specimen. The result of the primary specimen is reconfirmed if the split specimen meets these criteria.

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§40.183 What information do laboratories report to MROs regarding split specimen results?

(a) As the laboratory responsible for testing the split specimen, you must report split specimen test results by checking the "Reconfirmed" box or the "Failed to Reconfirm" box (Step 5(b)) on Copy 1 of the CCF.

(b) If you check the "Failed to Reconfirm" box, one of the following statements must be included (as appropriate) on the "Reason" line (Step 5(b)):

(1) "Drug(s)/Drug Metabolite(s) Not Detected."

(2) "Adulterant not found within criteria."

(3) "Specimen not consistent with substitution criteria [specify creatinine, specific gravity, or both]"

(4) "Specimen not available for testing."

(c) As the laboratory certifying scientist, enter your name, sign, and date the CCF.

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§40.185 Through what methods and to whom must a laboratory report split specimen results?

(a) As the laboratory testing the split specimen, 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 another service agent (*e.g.*, a C/TPA).

(b) 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.

(c) You must transmit the laboratory result to the MRO immediately, preferably on the same day or next business day as the result is signed and released.

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§40.187 What does the MRO do with split specimen laboratory results?

As an MRO, you must take the following actions when a laboratory reports the following results of split specimen tests:

(a) *Reconfirmed.* (1) In the case of a reconfirmed positive test for a drug or drug metabolite, report the reconfirmation to the DER and the employee.

(2) In the case of a reconfirmed adulterated or substituted result, report to the DER and the employee that the specimen was adulterated or substituted, either of which constitutes a refusal to test. Therefore, "refusal to test" is the final result.

(3) In the case of a reconfirmed substituted result, in which the creatinine concentration for the primary specimen was less than 2 mg/dL

and the creatinine concentration of the split specimen is between 2 and 5 mg/DL, inclusive, report the result to the employer as "dilute" and instruct the employer to conduct an immediate recollection under direct observation.

(b) *Failed to Reconfirm: Drug(s)/Drug Metabolite(s) Not Detected.* (1) Report to the DER and the employee that both tests must be cancelled.

(2) Using the format in Appendix D to this part, inform ODAPC of the failure to reconfirm.

(c) *Failed to Reconfirm: Adulteration or Substitution (as appropriate) Criteria Not Met.* (1) Report to the DER and the employee that both tests must be cancelled.

(2) Using the format in Appendix D to this part, inform ODAPC of the failure to reconfirm.

(d) *Failed to Reconfirm: Specimen not Available for Testing.* (1) Report to the DER and the employee that both tests must be cancelled and the reason for cancellation.

(2) Direct the DER to ensure the immediate collection of another specimen from the employee under direct observation, with no notice given to the employee of this collection requirement until immediately before the collection.

(3) Using the format in Appendix D to this part, notify ODAPC of the failure to reconfirm.

(e) Enter your name, sign and date (Step 7) of Copy 2 of the CCF.

(f) Send a legible copy of Copy 2 of the CCF (or a signed and dated letter, see §40.163) to the employer and keep a copy for your records. Transmit the document as provided in §40.167.

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000 as amended by Amdt. 40-11, 68 FR 31624, May 28, 2003]

§40.189 Where is other information concerning split specimens found in this regulation?

You can find more information concerning split specimens in several sections of this part:

§40.3–Definition.
§40.65–Quantity of split specimen.
§40.67–Directly observed test when split specimen is unavailable.
§§ 40.71-40.73–Collection process for split specimens.
§40.83–Laboratory accessioning of split specimens.
§40.99–Laboratory retention of split specimens.
§40.103–Blind split specimens.
§40.153–MRO notice to employees on tests of split specimen.
§§ 40.193 and 40.201–MRO actions on insufficient or unavailable split specimens.
Appendix D to Part 40–Report format for split specimen failure to reconfirm.

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

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 within a reasonable time, as determined by the employer, 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 C/TPA (see §40.61(a));

(2) Fail to remain at the testing site until the testing process is complete;

(3) Fail to provide a urine specimen for any drug test required by this part or DOT agency regulations;

(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 as part of the "shy bladder" procedures of this part (see §40.193(d)); or

(8) Fail to cooperate with any part of the testing process (*e.g.*, refuse to empty pockets when so directed by the collector, behave in a confrontational way that disrupts the collection process).

(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 (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 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 "refused to test because" box (Step 6) on Copy 2 of the CCF, and add the reason on the "Remarks" line. 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.

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000 as amended by Amdt. 40-11, 68 FR 31624, May 28, 2003]

§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.

(3) If the employee refuses to make the attempt to provide a new urine specimen, 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 working 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.

(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 "Refusal to test because" (Step 6) on the CCF and enter reason in the remarks line; and

(ii) Sign and date the CCF.

(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.

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§40.195 What happens when an individual is unable to provide a sufficient amount of urine for a pre-employment 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 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.

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§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 §40.145(a)(1)), 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) 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.

(4) 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.

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000 as amended by Amdt. 40-11, 68 FR 31624, May 28, 2003]

§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 .

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§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's test of the primary specimen is positive and the split specimen is reported by the laboratory as "Failure to Reconfirm: Drug(s)/Drug Metabolite(s) Not Detected." You must follow applicable procedures in §40.187(b) (no recollection is required in this case).

(d) The laboratory's test result for the primary specimen is adulterated or substituted and the split specimen is reported by the laboratory as "Adulterant not found within criteria," or " specimen not consistent with substitution criteria, as applicable. You must follow applicable procedures in §40.187(c) (no recollection is required in this case).

(e) The laboratory's test of the primary specimen is positive, adulterated, or substituted and the split specimen is unavailable for testing. You must follow applicable procedures in §40.187(d) (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).

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000 as amended by a second effective date in Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§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 are "correctable flaws" that laboratories must attempt to correct:

(1) The collector's signature is omitted on the certification statement on the CCF.

(2) The specimen temperature was not checked and the "Remarks" line did not contain an entry regarding the temperature being out of range.

(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 the laboratory copy of the CCF for a positive, adulterated, substituted, or invalid test result.

(3) The collector uses a non-DOT form for the test, provided that the collection and testing process is conducted in accordance with DOT procedures in an HHS-certified laboratory following DOT initial and confirmation test criteria.

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000 as amended by a second effective date in Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§40.205 How are drug test problems corrected?

(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, you must, as the person responsible for the use of the incorrect form, provide a signed statement that the incorrect form contains all the information needed for a valid DOT drug test, 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 for DOT tests. For this flaw to have been corrected, the test of the specimen must have occurred at a HHS-certified laboratory where it was tested using the testing protocol in 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.

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000 as amended by a second effective date in Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§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)).

(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).

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000 as amended by a second effective date in Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§40.209 What is the effect of procedural problems that are not sufficient to cancel a drug test?

(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);

(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 the laboratory copy); or

(10) Claims that the employee was improperly selected for testing.

(c) As an employer, these types of errors, even though not sufficient to cancel a drug test result, may subject you to enforcement action under DOT agency regulations.

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000 as amended by a second effective date in Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

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 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.

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000 as amended by a second effective date in Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§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 three consecutive error-free mock tests.

(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.

(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.

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000 as amended by a second effective date in Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§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.

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000 as amended by a second effective date in Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§40.217 Where is other information on the role of STTs and BATs found in this regulation?

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

§40.3–Definitions.
§40.223–Responsibility for supervising employees being tested.
§§ 40.225-40.227–Use of the alcohol testing form.
§§ 40.241-40.245–Screening test procedures with ASDs and EBTs.
§§ 40.251-40.255–Confirmation test procedures.
§40.261–Refusals to test.
§§ 40.263-40.265–Insufficient saliva or breath.
§40.267–Problems requiring cancellation of tests.
§§ 40.269-40.271–Correcting problems in tests.

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000 as amended by a second effective date in Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§40.219 [Removed]

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000 as amended by a second effective date in Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

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

§40.221 Where does an alcohol test take place?

(a) A DOT alcohol test must take place at an alcohol testing site meeting the requirements of this section.

(b) If you are operating an alcohol testing site, you must ensure that it meets the security requirements of §40.223.

(c) If you are operating an alcohol testing site, you must ensure that it provides visual and aural privacy to the employee being tested, sufficient to prevent unauthorized persons from seeing or hearing test results.

(d) If you are operating an alcohol testing site, you must ensure that it has all needed personnel, materials, equipment, and facilities to provide for the collection and analysis of breath and/or saliva samples, and a suitable clean surface for writing.

(e) If an alcohol testing site fully meeting all the visual and aural privacy requirements of paragraph (c) is not readily available, this part allows a reasonable suspicion or post-accident test to be conducted at a site that partially meets these requirements. In this case, the site must afford visual and aural privacy to the employee to the greatest extent practicable.

(f) An alcohol testing site can be in a medical facility, a mobile facility (*e.g.*, a van), a dedicated collection facility, or any other location meeting the requirements of this section.

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000 as amended by a second effective date in Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§40.223 What steps must be taken to protect the security of alcohol testing sites?

(a) If you are a BAT, STT, or other person operating an alcohol testing site, you must prevent unauthorized personnel from entering the testing site.

(1) The only people you are to treat as authorized persons are employees being tested, BATs, STTs, and other alcohol testing site workers, DERs, employee representatives authorized by the employer (*e.g.*, on the basis of employer policy or labor-management agreement), and DOT agency representatives.

(2) You must ensure that all persons are under the supervision of a BAT or STT at all times when permitted into the site.

(3) You may remove any person who obstructs, interferes with, or causes unnecessary delay in the testing process.

(b) As the BAT or STT, you must not allow any person other than you, the employee, or a DOT agency representative to actually witness the testing process (see §§ 40.241-40.255).

(c) If you are operating an alcohol testing site, you must ensure that when an EBT or ASD is not being used for testing, you store it in a secure place.

(d) If you are operating an alcohol testing site, you must ensure that no one other than BATs or other employees of the site have access to the site when an EBT is unsecured.

(e) As a BAT or STT, to avoid distraction that could compromise security, you are limited to conducting an alcohol test for only one employee at a time.

(1) When an EBT screening test on an employee indicates an alcohol concentration of 0.02 or higher, and the same EBT will be used for the confirmation test, you are not allowed to use the EBT for a test on another employee before completing the confirmation test on the first employee.

(2) As a BAT who will conduct both the screening and the confirmation test, you are to complete the entire screening and confirmation process on one employee before starting the screening process on another employee.

(3) You are not allowed to leave the alcohol testing site while the testing process for a given employee is in progress, except to notify a supervisor or contact a DER for assistance in the case an employee or other person who obstructs, interferes with, or unnecessarily delays the testing process.

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000 as amended by a second effective date in Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§40.225 What form is used for an alcohol test?

(a) The DOT Alcohol Testing Form (ATF) must be used for every DOT alcohol test. The ATF must be a three-part carbonless manifold form. The ATF is found in Appendix G to this part. You may view this form on the ODAPC web site (http://www.dot.gov/ost/dapc).

(b) As an employer in the DOT alcohol testing program, you are not permitted to modify or revise the ATF except as follows:

(1) You may include other information needed for billing purposes, outside the boundaries of the form.

(2) You may use a ATF directly generated by an EBT which omits the space for affixing a separate printed result to the ATF, provided the EBT prints the result directly on the ATF.

(3) You may use an ATF that has the employer's name, address, and telephone number preprinted. In addition, a C/TPA's name, address, and telephone number may be included, to assist with negative results.

(4) You may use an ATF in which all pages are printed on white paper. The white pages must have either clearly discernible borders in the specified color for each page or designation statements for each copy in the specified color.

(5) As a BAT or STT, you may add, on the "Remarks" line of the ATF, the name of the DOT agency under whose authority the test occurred.

(6) As a BAT or STT, you may use a ATF that has your name, address, and telephone number preprinted, but under no circumstances can your signature be preprinted.

(c) As an employer, you may use an equivalent foreign-language version of the ATF approved by ODAPC. You may use such a non-English language form only in a situation where both the employee and BAT/STT understand and can use the form in that language.

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000 as amended by a second effective date in Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§40.227 May employers use the ATF for non-DOT tests, or non-DOT forms for DOT tests?

(a) No, as an employer, BAT, or STT, you are prohibited from using the ATF for non-DOT alcohol tests. You are also prohibited from using non-DOT forms for DOT alcohol tests. Doing either subjects you to enforcement action under DOT agency regulations.

(b) If the STT or BAT, either by mistake, or as the only means to conduct a test under difficult circumstances (*e.g.*, post-accident test with insufficient time to obtain the ATF), uses a non-DOT form for a DOT test, the use of a non-DOT form does not, in and of itself, require the employer or service agent to cancel the test. However, in order for the test to be considered valid, a signed statement must be obtained from the STT or BAT in accordance with §40.271(b) .

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§40.229 What devices are used to conduct alcohol screening tests?

EBTs and ASDs on the NHTSA conforming products lists (CPL) for evidential and non-evidential devices are the only devices you are allowed to use to conduct alcohol screening tests under this part. An ASD can be used only for screening tests for alcohol, and may not be used for confirmation tests.

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§40.231 What devices are used to conduct alcohol confirmation tests?

(a) EBTs on the NHTSA CPL for evidential devices that meet the requirements of paragraph (b) of this section are the only devices you may use to conduct alcohol confirmation tests under this part. Note that, among devices on the CPL for EBTs, only those devices listed without an asterisk (*) are authorized for use in confirmation testing in the DOT alcohol testing program.

(b) To conduct a confirmation test, you must use an EBT that has the following capabilities:

(1) Provides a printed triplicate result (or three consecutive identical copies of a result) of each breath test;

(2) Assigns a unique number to each completed test, which the BAT and employee can read before each test and which is printed on each copy of the result;

(3) Prints, on each copy of the result, the manufacturer's name for the device, its serial number, and the time of the test;

(4) Distinguishes alcohol from acetone at the 0.02 alcohol concentration level;

(5) Tests an air blank; and

(6) Performs an external calibration check.

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§40.233 What are the requirements for proper use and care of EBTs?

(a) As an EBT manufacturer, you must submit, for NHTSA approval, a quality assurance plan (QAP) for your EBT before NHTSA places the EBT on the CPL.

(1) Your QAP must specify the methods used to perform external calibration checks on the EBT, the tolerances within which the EBT is regarded as being in proper calibration, and the intervals at which these checks must be performed. In designating these intervals, your QAP must take into account factors like frequency of use, environmental conditions (*e.g.*, temperature, humidity, altitude) and type of operation (*e.g.*, stationary or mobile).

(2) Your QAP must also specify the inspection, maintenance, and calibration requirements and intervals for the EBT.

(b) As the manufacturer, you must include, with each EBT, instructions for its use and care consistent with the QAP.

(c) As the user of the EBT (*e.g.*, employer, service agent), you must do the following:

(1) You must follow the manufacturer's instructions (see paragraph (b) of this section), including performance of external calibration checks at the intervals the instructions specify.

(2) In conducting external calibration checks, you must use only calibration devices appearing on NHTSA's CPL for "Calibrating Units for Breath Alcohol Tests."

(3) If an EBT fails an external check of calibration, you must take the EBT out of service. You may not use the EBT again for DOT alcohol testing until it is repaired and passes an external calibration check.

(4) You must maintain records of the inspection, maintenance, and calibration of EBTs as provided in §40.333(a)(2) .

(5) You must ensure that inspection, maintenance, and calibration of the EBT are performed by its manufacturer or a maintenance representative certified either by the manufacturer or by a state health agency or other appropriate state agency.

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§40.235 What are the requirements for proper use and care of ASDs?

(a) As an ASD manufacturer, you must submit, for NHTSA approval, a QAP for your ASD before NHTSA places the ASD on the CPL. Your QAP must specify the methods used for quality control checks, temperatures at which the ASD must be stored and used, the shelf life of the device, and environmental conditions (*e.g.*, temperature, altitude, humidity) that may affect the ASD's performance.

(b) As a manufacturer, you must include with each ASD instructions for its use and care consistent with the QAP. The instructions must include directions on the proper use of the ASD, and, where applicable the time within which the device must be read, and the manner in which the reading is made.

(c) As the user of the ADS (*e.g.*, employer, STT), you must follow the QAP instructions.

(d) You are not permitted to use an ASD that does not pass the specified quality control checks or that has passed its expiration date.

(e) As an employer, with respect to breath ASDs, you must also follow the device use and care requirements of §40.233 .

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

Subpart L–Alcohol Screening Tests

§40.241 What are the first steps in any alcohol screening test?

As the BAT or STT you will take the following steps to begin all alcohol screening tests, regardless of the type of testing device you are using:

(a) When a specific time for an employee's test has been scheduled, or the collection site is at the employee's work site, and the employee does not appear at the collection site at the scheduled time, contact the DER to determine the appropriate interval within which the DER has determined the employee is authorized to arrive. If the employee's arrival is delayed beyond that time, you must notify the DER that the employee has not reported for testing. In a situation where a C/TPA has notified an owner/operator or other individual employee to report for testing and the employee does not appear, the C/TPA must notify the employee that he or she has refused to test.

(b) Ensure that, when the employee enters the alcohol testing site, you begin the alcohol testing process without undue delay. For example, you must not wait because the employee says he or she is not ready or because an authorized employer or employee representative is delayed in arriving.

(1) If the employee is also going to take a DOT drug test, you must, to the greatest extent practicable, ensure that the alcohol test is completed before the urine collection process begins.

(2) If the employee needs medical attention (*e.g.*, an injured employee in an emergency medical facility who is required to have a post-accident test), do not delay this treatment to conduct a test.

(c) Require the employee to provide positive identification. You must see a photo ID issued by the employer (other than in the case of an owner-operator or other self-employer individual) or a Federal, state, or local government (*e.g.*, a driver's license). You may not accept faxes or photocopies of identification. Positive identification by an employer representative (not a co-worker or another employee being tested) is also acceptable. If the employee cannot produce positive identification, you must contact a DER to verify the identity of the employee.

(d) If the employee asks, provide your identification to the employee. Your identification must include your name and your employer's name but is not required to include your picture, address, or telephone number.

(e) Explain the testing procedure to the employee, including showing the employee the instructions on the back of the ATF.

(f) Complete Step 1 of the ATF.

(g) Direct the employee to complete Step 2 on the ATF and sign the certification. If the employee refuses to sign this certification, you must document this refusal on the "Remarks" line of the ATF and immediately notify the DER. This is a refusal to test.

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§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 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.

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§40.245 What is the procedure for an alcohol screening test using a saliva ASD?

As the STT, you must take the following steps:

(a) Check the expiration date on the device and show it to the employee. You may not use the device after its expiration date.

(b) Open an individually wrapped or sealed package containing the device in the presence of the employee.

(c) 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.

(d) 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 (g) 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.

(e) 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.

(f)(1) If you were unable to successfully follow the procedures of paragraphs (c) through (e) 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.

(2) The new device you use must be one that has been under your control or that of the employer before the test.

(3) 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.)

(4) 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.

(5) If you are unable to successfully follow the procedures of paragraphs (c) through (e) of this section on the new test, you must end the collection and put an explanation on the "Remarks" line of the ATF.

(6) You must then direct the employee to take a new test immediately, using an EBT for the screening test.

(g) If you are able to successfully follow the procedures of paragraphs (c)-(e) 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 (f) of this section. In this case, you must place the device into the employee's mouth to collect saliva for the new test.

(h) 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.

(i) You must never re-use devices, swabs, gloves or other materials used in saliva testing.

(j) You must note the fact that you used a saliva ASD in Step 3 of the ATF.

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§40.247 What procedures does the BAT or STT follow after a screening test result?

(a) If the test result is an alcohol concentration of less than 0.02, as the BAT or STT, you must do the following:

(1) Sign and date Step 3 of the ATF; and

(2) Transmit the result to the DER in a confidential manner, as provided in §40.255 .

(b) If the test result is an alcohol concentration of 0.02 or higher, as the BAT or STT, you must direct the employee to take a confirmation test.

(1) If you are the BAT who will conduct the confirmation test, you must then conduct the test using the procedures beginning at §40.251 .

(2) If you are not the BAT who will conduct the confirmation test, direct the employee to take a confirmation test, sign and date Step 3 of the ATF, and give the employee Copy 2 of the ATF.

(3) If the confirmation test will be performed at a different site from the screening test, you must take the following additional steps:

(i) Advise the employee not to eat, drink, put anything (*e.g.*, cigarette, chewing gum) into his or her mouth, or belch;

(ii) Tell the employee the reason for the waiting period required by §40.251(a) (*i.e.*, to prevent an accumulation of mouth alcohol from leading to an artificially high reading);

(iii) Explain that following your instructions concerning the waiting period is to the employee's benefit;

(iv) Explain that the confirmation test will be conducted at the end of the waiting period, even if the instructions have not been followed;

(v) Note on the "Remarks" line of the ATF that the waiting period instructions were provided;

(vi) Instruct the person accompanying the employee to carry a copy of the ATF to the BAT who will perform the confirmation test; and

(vii) Ensure that you or another BAT, STT, or employer representative observe the employee as he or she is transported to the confirmation testing site. You must direct the employee not to attempt to drive a motor vehicle to the confirmation testing site.

(c) If the screening test is invalid, you must, as the BAT or STT, tell the employee the test is cancelled and note the problem on the "Remarks" line of the ATF. If practicable, repeat the testing process (see §40. 271).

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

Subpart M–Alcohol Confirmation Tests

§40.251 What are the first steps in an alcohol confirmation test?

As the BAT for an alcohol confirmation test, you must follow these steps to begin the confirmation test process:

(a) You must carry out a requirement for a waiting period before the confirmation test, by taking the following steps:

(1) You must ensure that the waiting period lasts at least 15 minutes, starting with the completion of the screening test. After the waiting period has elapsed, you should begin the confirmation test as soon as possible, but not more than 30 minutes after the completion of the screening test.

(i) If the confirmation test is taking place at a different location from the screening test (see §40.247(b)(3)) the time of transit between sites counts toward the waiting period if the STT or BAT who conducted the screening test provided the waiting period instructions.

(ii) If you cannot verify, through review of the ATF, that waiting period instructions were provided, then you must carry out the waiting period requirement.

(iii) You or another BAT or STT, or an employer representative, must observe the employee during the waiting period.

(2) Concerning the waiting period, you must tell the employee:

(i) Not to eat, drink, put anything (*e.g.*, cigarette, chewing gum) into his or her mouth, or belch;

(ii) The reason for the waiting period (*i.e.*, to prevent an accumulation of mouth alcohol from leading to an artificially high reading);

(iii) That following your instructions concerning the waiting period is to the employee's benefit; and

(iv) That the confirmation test will be conducted at the end of the waiting period, even if the instructions have not been followed.

(3) If you become aware that the employee has not followed the instructions, you must note this on the "Remarks" line of the ATF.

(b) If you did not conduct the screening test for the employee, you must require positive identification of the employee, explain the confirmation procedures, and use a new ATF. You must note on the "Remarks" line of the ATF that a different BAT or STT conducted the screening test.

(c) Complete Step 1 of the ATF.

(d) Direct the employee to complete Step 2 on the ATF and sign the certification. If the employee refuses to sign this certification, you must document this refusal on the "Remarks" line of the ATF and immediately notify the DER. This is a refusal to test.

(e) Even if more than 30 minutes have passed since the screening test result was obtained, you must begin the confirmation test procedures in §40.253, not another screening test.

(f) You must note on the "Remarks" line of the ATF the time that elapsed between the two events, and if the confirmation test could not begin within 30 minutes of the screening test, the reason why.

(g) Beginning the confirmation test procedures after the 30 minutes have elapsed does not invalidate the screening or confirmation tests, but it may constitute a regulatory violation subject to DOT agency sanction.

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§40.253 What are the procedures for conducting an alcohol confirmation test?

As the BAT conducting an alcohol confirmation test, you must follow these steps in order to complete the confirmation test process:

(a) In the presence of the employee, you must conduct an air blank on the EBT you are using before beginning the confirmation test and show the reading to the employee.

(1) If the reading is 0.00, the test may proceed. If the reading is greater than 0.00, you must conduct another air blank.

(2) If the reading on the second air blank is 0.00, the test may proceed. If the reading is greater than 0.00, you must take the EBT out of service.

(3) If you take an EBT out of service for this reason, no one may use it for testing until the EBT is found to be within tolerance limits on an external check of calibration.

(4) You must proceed with the test of the employee using another EBT, if one is available.

(b) You must open a new individually wrapped or sealed mouthpiece in view of the

employee and insert it into the device in accordance with the manufacturer's instructions.

(c) You must ensure that you and the employee read the sequential test number displayed on the EBT.

(d) You must 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.

(e) You must show the employee the result displayed on the EBT.

(f) You must show the employee the result and unique test number that the EBT prints out either directly onto the ATF or onto a separate printout.

(g) If the EBT provides a separate printout of the result, you must attach the printout to the designated space on the ATF with tamper-evident tape, or use a self-adhesive label that is tamper-evident.

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§40.255 What happens next after the alcohol confirmation test result?

(a) After the EBT has printed the result of an alcohol confirmation test, you must, as the BAT, take the following additional steps:

(1) Sign and date Step 3 of the ATF.

(2) If the alcohol confirmation test result is lower than 0.02, nothing further is required of the employee. As the BAT, you must sign and date Step 3 of the ATF.

(3) If the alcohol confirmation test result is 0.02 or higher, direct the employee to sign and date Step 4 of the ATF. If the employee does not do so, you must note this on the "Remarks" line of the ATF. However, this is not considered a refusal to test.

(4) If the test is invalid, tell the employee the test is cancelled and note the problem on the "Remarks" line of the ATF. If practicable, conduct a re-test. (see §40.271).

(5) Immediately transmit the result directly to the DER in a confidential manner.

(i) You may transmit the results using Copy 1 of the ATF, in person, by telephone, or by electronic means. In any case, you must immediately notify the DER of any result of 0.02 or greater by any means (*e.g.*, telephone or secure fax machine) that ensures the result is immediately received by the DER. You must not transmit these results through C/TPAs or other service agents.

(ii) If you do not make the initial transmission in writing, you must follow up the initial transmission with Copy 1 of the ATF.

(b) As an employer, you must take the following steps with respect to the receipt and storage of alcohol test result information:

(1) If you receive any test results that are not in writing (*e.g.*, by telephone or electronic means), you must establish a mechanism to establish the identity of the BAT sending you the results.

(2) You must store all test result information in a way that protects confidentiality.

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

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 within a reasonable time, as determined by the employer, 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 C/TPA (see §40.241(b)(1));

(2) Fail to remain at the testing site until the testing process is complete;

(3) Fail to attempt to provide a saliva or breath specimen, as applicable, for any test required by this part or DOT agency regulations;

(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(b)(7)); 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.

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§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.

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§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 itermediary). 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.

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§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:

(1) The STT reads the result either sooner than or later than the time allotted by the manufacturer (see §40.245(h));

(2) The device does not activate (see §40.245(g)); or

(3) The device is used for a test after the expiration date printed on its package (see §40.245(a)).

(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 (d)).

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§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)).

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§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.

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§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).

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§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.

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§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.

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

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; or

(5) 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).

(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 education and/or treatment, the follow-up evaluation, continuing treatment recommendations, and the follow-up testing plan;

(vii) SAP consultation and communication with employers, MROs, and treatment providers;

(viii) Reporting and recordkeeping requirements;

(ix) 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.

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§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 §40.281(a)(5), 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.

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§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.

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§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.

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§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.

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§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.

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§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.

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§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.

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§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).

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§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).

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§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 asssitance. 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.

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000 as amended by a second effective date in Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§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.

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000 as amended by a second effective date in Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§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.

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000 as amended by a second effective date in Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§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.

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000 as amended by a second effective date in Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§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.

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000 as amended by a second effective date in Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§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.

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000 as amended by a second effective date in Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§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.

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000 as amended by a second effective date in Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

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.

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000 as amended by a second effective date in Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§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 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.

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000 as amended by a second effective date in Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§40.325 [Reserved]

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§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.

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000 as amended by a second effective date in Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§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).

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000 as amended by a second effective date in Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§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.

(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.

(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.

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000 as amended by a second effective date in Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§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 employee alcohol test results indicating an alcohol concentration of 0.02 or greater;

(ii) Records of employee 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).

(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 working days.

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000 as amended by a second effective date in Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§§ 40.335 – 40.339 [Reserved]

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

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.

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000 as amended by a second effective date in Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§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.

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000 as amended by a second effective date in Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§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 .

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000 as amended by a second effective date in Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§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.

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000 as amended by a second effective date in Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§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 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.

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000 as amended by a second effective date in Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§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 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.

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000 as amended by a second effective date in Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§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.

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000 as amended by a second effective date in Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§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).

(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 are authorized by a DOT agency regulation to do so, 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 the laboratory copy 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 RSPA 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.

§§ 40.337 – 40.359 [Reserved]

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

Subpart R–Public Interest Exclusions

§40.361 What is the purpose of a public interest exclusion (PIE)?

(a) To protect the public interest, including protecting transportation employers and employees from serious noncompliance with DOT drug and alcohol testing rules, the Department's policy is to ensure that employers conduct business only with responsible service agents.

(b) The Department therefore uses PIEs to exclude from participation in DOT's drug and alcohol testing program any service agent who, by serious noncompliance with this part or other DOT agency drug and alcohol testing regulations, has shown that it is not currently acting in a responsible manner.

(c) A PIE is a serious action that the Department takes only to protect the public interest. We intend to use PIEs only to remedy situations of serious noncompliance. PIEs are not used for the purpose of punishment.

(d) Nothing in this subpart precludes a DOT agency or the Inspector General from taking other action authorized by its regulations with respect to service agents or employers that violate its regulations.

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000 as amended by a second effective date in Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§40.363 On what basis may the Department issue a PIE?

(a) If you are a service agent, the Department may issue a PIE concerning you if we determine that you have failed or refused to provide drug or alcohol testing services consistent with the requirements of this part or a DOT agency drug and alcohol regulation.

(b) The Department also may issue a PIE if you have failed to cooperate with DOT agency representatives concerning inspections, complaint investigations, compliance and enforcement reviews, or requests for documents and other information about compliance with this part or DOT agency drug and alcohol regulations.

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000 as amended by a second effective date in Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§40.365 What is the Department's policy concerning starting a PIE proceeding?

(a) It is the Department's policy to start a PIE proceeding only in cases of serious, uncorrected noncompliance with the provisions of this part, affecting such matters as safety, the outcomes of test results, privacy and confidentiality, due process and fairness for employees, the honesty and integrity of the testing program, and cooperation with or provision of information to DOT agency representatives.

(b) The following are examples of the kinds of serious noncompliance that, as a matter of policy, the Department views as appropriate grounds for starting a PIE proceeding. These examples are not intended to be an exhaustive or exclusive list of the grounds for starting a PIE proceeding. We intend them to illustrate the level of seriousness that the Department believes supports starting a PIE proceeding. The examples follow:

(1) For an MRO, verifying tests positive without interviewing the employees as required by this part or providing MRO services without meeting the qualifications for an MRO required by this part;

(2) For a laboratory, refusing to provide information to the Department, an employer, or an employee as required by this part; failing or refusing to conduct a validity testing program when required by this part; or a pattern or practice of testing errors that result in the cancellation of tests. (As a general matter of

policy, the Department does not intend to initiate a PIE proceeding concerning a laboratory with respect to matters on which HHS initiates certification actions under its laboratory guidelines.);

(3) For a collector, a pattern or practice of directly observing collections when doing so is unauthorized, or failing or refusing to directly observe collections when doing so is mandatory;

(4) For collectors, BATs, or STTs, a pattern or practice of using forms, testing equipment, or collection kits that do not meet the standards in this part;

(5) For a collector, BAT, or STT, a pattern or practice of "fatal flaws" or other significant uncorrected errors in the collection process;

(6) For a laboratory, MRO or C/TPA, failing or refusing to report tests results as required by this part or DOT agency regulations;

(7) For a laboratory, falsifying, concealing, or destroying documentation concerning any part of the drug testing process, including, but not limited to, documents in a "litigation package";

(8) For SAPs, providing SAP services while not meeting SAP qualifications required by this part or performing evaluations without face-to-face interviews;

(9) For any service agent, maintaining a relationship with another party that constitutes a conflict of interest under this part (*e.g.*, a laboratory that derives a financial benefit from having an employer use a specific MRO);

(10) For any service agent, representing falsely that the service agent or its activities is approved or certified by the Department or a DOT agency;

(11) For any service agent, disclosing an employee's test result information to any party this part or a DOT agency regulation does not authorize, including by obtaining a "blanket" consent from employees or by creating a data base from which employers or others can retrieve an employee's DOT test results without the specific consent of the employee;

(12) For any service agent, interfering or attempting to interfere with the ability of an MRO to communicate with the Department, or retaliating against an MRO for communicating with the Department;

(13) For any service agent, directing or recommending that an employer fail or refuse to implement any provision of this part; or

(14) With respect to noncompliance with a DOT agency regulation, conduct that affects important provisions of Department-wide concern (*e.g.*, failure to properly conduct the selection process for random testing).

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000 as amended by a second effective date in Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§40.367 Who initiates a PIE proceeding?

The following DOT officials may initiate a PIE proceeding:

(a) The drug and alcohol program manager of a DOT agency;

(b) An official of ODAPC, other than the Director; or

(c) The designee of any of these officials.

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000 as amended by a second effective date in Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§40.369 What is the discretion of an initiating official in starting a PIE proceeding?

(a) Initiating officials have broad discretion in deciding whether to start a PIE proceeding.

(b) In exercising this discretion, the initiating official must consider the Department's policy regarding the seriousness of the service agent's conduct (see §40.365) and all information he or she has obtained to this point concerning the facts of the case. The initiating official may also consider the availability of the resources needed to pursue a PIE proceeding.

(c) A decision not to initiate a PIE proceeding does not necessarily mean that the

Department regards a service agent as being in compliance or that the Department may not use other applicable remedies in a situation of noncompliance.

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000 as amended by a second effective date in Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§40.371 On what information does an initiating official rely in deciding whether to start a PIE proceeding?

(a) An initiating official may rely on credible information from any source as the basis for starting a PIE proceeding.

(b) Before sending a correction notice (see §40.373), the initiating official informally contacts the service agent to determine if there is any information that may affect the initiating official's determination about whether it is necessary to send a correction notice. The initiating official may take any information resulting from this contact into account in determining whether to proceed under this subpart.

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000 as amended by a second effective date in Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§40.373 Before starting a PIE proceeding, does the initiating official give the service agent an opportunity to correct problems?

(a) If you are a service agent, the initiating official must send you a correction notice before starting a PIE proceeding.

(b) The correction notice identifies the specific areas in which you must come into compliance in order to avoid being subject to a PIE proceeding.

(c) If you make and document changes needed to come into compliance in the areas listed in the correction notice to the satisfaction of the initiating official within 60 days of the date you receive the notice, the initiating official does not start a PIE proceeding. The initiating official may conduct appropriate fact finding to verify that you have made and maintained satisfactory corrections. When he or she is satisfied that you are in compliance, the initiating official sends you a notice that the matter is concluded.

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000 as amended by a second effective date in Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§40.375 How does the initiating official start a PIE proceeding?

(a) As a service agent, if your compliance matter is not correctable (see §40.373(a)), or if have not resolved compliance matters as provided in §40.373(c), the initiating official starts a PIE proceeding by sending you a notice of proposed exclusion (NOPE). The NOPE contains the initiating official's recommendations concerning the issuance of a PIE, but it is not a decision by the Department to issue a PIE.

(b) The NOPE includes the following information:

(1) A statement that the initiating official is recommending that the Department issue a PIE concerning you;

(2) The factual basis for the initiating official's belief that you are not providing drug and/or alcohol testing services to DOT-regulated employers consistent with the requirements of this part or are in serious noncompliance with a DOT agency drug and alcohol regulation;

(3) The factual basis for the initiating official's belief that your noncompliance has not been or cannot be corrected;

(4) The initiating official's recommendation for the scope of the PIE;

(5) The initiating official's recommendation for the duration of the PIE; and

(6) A statement that you may contest the issuance of the proposed PIE, as provided in §40.379.

(c) The initiating official sends a copy of the NOPE to the ODAPC Director at the same time he or she sends the NOPE to you.

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000 as amended by a second effective date in Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§40.377 Who decides whether to issue a PIE?

(a) The ODAPC Director, or his or her designee, decides whether to issue a PIE. If a designee is acting as the decision maker, all references in this subpart to the Director refer to the designee.

(b) To ensure his or her impartiality, the Director plays no role in the initiating official's determination about whether to start a PIE proceeding.

(c) There is a “firewall” between the initiating official and the Director. This means that the initiating official and the Director are prohibited from having any discussion, contact, or exchange of information with one another about the matter, except for documents and discussions that are part of the record of the proceeding.

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000 as amended by a second effective date in Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§40.379 How do you contest the issuance of a PIE?

(a) If you receive a NOPE, you may contest the issuance of the PIE.

(b) If you want to contest the proposed PIE, you must provide the Director information and argument in opposition to the proposed PIE in writing, in person, and/or through a representative. To contest the proposed PIE, you must take one or more of the steps listed in this paragraph (b) within 30 days after you receive the NOPE.

(1) You may request that the Director dismiss the proposed PIE without further proceedings, on the basis that it does not concern serious noncompliance with this part or DOT agency regulations, consistent with the Department's policy as stated in §40.365.

(2) You may present written information and arguments, consistent with the provisions of §40.381, contesting the proposed PIE.

(3) You may arrange with the Director for an informal meeting to present your information and arguments.

(c) If you do not take any of the actions listed in paragraph (b) of this section within 30 days after you receive the NOPE, the matter proceeds as an uncontested case. In this event, the Director makes his or her decision based on the record provided by the initiating official (*i.e.*, the NOPE and any supporting information or testimony) and any additional information the Director obtains.

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000 as amended by a second effective date in Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§40.381 What information do you present to contest the proposed issuance of a PIE?

(a) As a service agent who wants to contest a proposed PIE, you must present at least the following information to the Director:

(1) Specific facts that contradict the statements contained in the NOPE (see §40.375(b)(2) and (3)). A general denial is insufficient to raise a genuine dispute over facts material to the issuance of a PIE;

(2) Identification of any existing, proposed or prior PIE; and

(3) Identification of your affiliates, if any.

(b) You may provide any information and arguments you wish concerning the proposed issuance, scope and duration of the PIE (see §40.375(b)(4) and (5)).

(c) You may provide any additional relevant information or arguments concerning any of the issues in the matter.

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000 as amended by a second effective date in Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§40.383 What procedures apply if you contest the issuance of a PIE?

(a) DOT conducts PIE proceedings in a fair and informal manner. The Director may use flexible procedures to allow you to present matters in opposition. The Director is not required to follow formal rules of evidence or procedure in creating the record of the proceeding.

(b) The Director will consider any information or argument he or she determines to be relevant to the decision on the matter.

(c) You may submit any documentary evidence you want the Director to consider. In addition, if you have arranged an informal meeting with the Director, you may present witnesses and confront any person the initiating official presents as a witness against you.

(d) In cases where there are material factual issues in dispute, the Director or his or her designee may conduct additional fact-finding.

(e) If you have arranged a meeting with the Director, the Director will make a transcribed record of the meeting available to you on your request. You must pay the cost of transcribing and copying the meeting record.

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000 as amended by a second effective date in Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§40.385 Who bears the burden of proof in a PIE proceeding?

(a) As the proponent of issuing a PIE, the initiating official bears the burden of proof.

(b) This burden is to demonstrate, by a preponderance of the evidence, that the service agent was in serious noncompliance with the requirements of this part for drug and/or alcohol testing-related services or with the requirements of another DOT agency drug and alcohol testing regulation.

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000 as amended by a second effective date in Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§40.387 What matters does the Director decide concerning a proposed PIE?

(a) Following the service agent's response (see §40.379(b)) or, if no response is received, after 30 days have passed from the date on which the service agent received the NOPE, the Director may take one of the following steps:

(1) In response to a request from the service agent (see §40.379(b)(1)) or on his or her own motion, the Director may dismiss a PIE proceeding if he or she determines that it does not concern serious noncompliance with this part or DOT agency regulations, consistent with the Department's policy as stated in §40.365.

(i) If the Director dismisses a proposed PIE under this paragraph (a), the action is closed with respect to the noncompliance alleged in the NOPE.

(ii) The Department may initiate a new PIE proceeding against you on the basis of different or subsequent conduct that is in noncompliance with this part or other DOT drug and alcohol testing rules.

(2) If the Director determines that the initiating official's submission does not have complete information needed for a decision, the Director may remand the matter to the initiating official. The initiating official may resubmit the matter to the Director when the needed information is complete. If the basis for the proposed PIE has changed, the initiating official must send an amended NOPE to the service agent.

(b) The Director makes determinations concerning the following matters in any PIE proceeding that he or she decides on the merits:

(1) Any material facts that are in dispute;

(2) Whether the facts support issuing a PIE;

(3) The scope of any PIE that is issued; and

(4) The duration of any PIE that is issued.

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000 as amended by a second effective date in Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§40.389 What factors may the Director consider?

This section lists examples of the kind of mitigating and aggravating factors that the Director may consider in determining whether to issue a PIE concerning you, as well as the scope and duration of a PIE. This list is not exhaustive or exclusive. The Director may consider other factors if appropriate in the circumstances of a particular case. The list of examples follows:

(a) The actual or potential harm that results or may result from your noncompliance;

(b) The frequency of incidents and/or duration of the noncompliance;

(c) Whether there is a pattern or prior history of noncompliance;

(d) Whether the noncompliance was pervasive within your organization, including such factors as the following:

(1) Whether and to what extent your organization planned, initiated, or carried out the noncompliance;

(2) The positions held by individuals involved in the noncompliance, and whether your principals tolerated their noncompliance; and

(3) Whether you had effective standards of conduct and control systems (both with respect to your own organization and any contractors or affiliates) at the time the noncompliance occurred;

(e) Whether you have demonstrated an appropriate compliance disposition, including such factors as the following:

(1) Whether you have accepted responsibility for the noncompliance and recognize the seriousness of the conduct that led to the cause for issuance of the PIE;

(2) Whether you have cooperated fully with the Department during the investigation. The Director may consider when the cooperation began and whether you disclosed all pertinent information known to you;

(3) Whether you have fully investigated the circumstances of the noncompliance forming the basis for the PIE and, if so, have made the result of the investigation available to the Director;

(4) Whether you have taken appropriate disciplinary action against the individuals responsible for the activity that constitutes the grounds for issuance of the PIE; and

(5) Whether your organization has taken appropriate corrective actions or remedial measures, including implementing actions to prevent recurrence;

(f) With respect to noncompliance with a DOT agency regulation, the degree to which the noncompliance affects matters common to the DOT drug and alcohol testing program;

(g) Other factors appropriate to the circumstances of the case.

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000 as amended by a second effective date in Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§40.391 What is the scope of a PIE?

(a) The scope of a PIE is the Department's determination about the divisions, organizational elements, types of services, affiliates, and/
or individuals (including direct employees of a service agent and its contractors) to which a PIE applies.

(b) If, as a service agent, the Department issues a PIE concerning you, the PIE applies to all your divisions, organizational elements, and types of services that are involved with or affected by the noncompliance that forms the factual basis for issuing the PIE.

(c) In the NOPE (see §40.375(b)(4)), the initiating official sets forth his or her recommendation for the scope of the PIE. The proposed scope of the PIE is one of the elements of the proceeding that the service agent may contest (see §40.381(b)) and about which the Director makes a decision (see §40.387(b)(3)).

(d) In recommending and deciding the scope of the PIE, the initiating official and Director, respectively, must take into account the provisions of paragraphs (e) through (j) of this section.

(e) The pervasiveness of the noncompliance within a service agent's organization (see §40.389(d)) is an important consideration in determining the scope of a PIE. The appropriate scope of a PIE grows broader as the pervasiveness of the noncompliance increases.

(f) The application of a PIE is not limited to the specific location or employer at which the conduct that forms the factual basis for issuing the PIE was discovered.

(g) A PIE applies to your affiliates, if the affiliate is involved with or affected by the conduct that forms the factual basis for issuing the PIE.

(h) A PIE applies to individuals who are officers, employees, directors, shareholders, partners, or other individuals associated with your organization in the following circumstances:

(1) Conduct forming any part of the factual basis of the PIE occurred in connection with the individual's performance of duties by or on behalf of your organization; or

(2) The individual knew of, had reason to know of, approved, or acquiesced in such conduct. The individual's acceptance of benefits derived from such conduct is evidence of such knowledge, acquiescence, or approval.

(i) If a contractor to your organization is solely responsible for the conduct that forms the factual basis for a PIE, the PIE does not apply to the service agent itself unless the service agent knew or should have known about the conduct and did not take action to correct it.

(j) PIEs do not apply to drug and alcohol testing that DOT does not regulate.

(k) The following examples illustrate how the Department intends the provisions of this section to work:

Example 1 to §40.391. Service Agent P provides a variety of drug testing services. P's SAP services are involved in a serious violation of this Part 40. However, P's other services fully comply with this part, and P's overall management did not plan or concur in the noncompliance, which in fact was contrary to P's articulated standards. Because the noncompliance was isolated in one area of the organization's activities, and did not pervade the entire organization, the scope of the PIE could be limited to SAP services.

Example 2 to §40.391. Service Agent Q provides a similar variety of services. The conduct forming the factual basis for a PIE concerns collections for a transit authority. As in Example 1, the noncompliance is not pervasive throughout Q's organization. The PIE would apply to collections at all locations served by Q, not just the particular transit authority or not just in the state in which the transit authority is located.

Example 3 to §40.391. Service Agent R provides a similar array of services. One or more of the following problems exists: R's activities in several areas–collections, MROs, SAPs, protecting the confidentiality of information–are involved in serious noncompliance; DOT determines that R's management knew or should have known about serious noncompliance in one or more areas, but management did not take timely corrective action; or, in response to an inquiry from DOT personnel, R's management refuses to provide information about its operations. In each of these three cases, the scope of the PIE would include all aspects of R's services.

Example 4 to §40.391. Service Agent W provides only one kind of service (*e.g.*, laboratory or MRO services). The Department issues a PIE concerning these services. Because W only provides this one kind of

service, the PIE necessarily applies to all its operations.

Example 5 to §40.391. Service Agent X, by exercising reasonably prudent oversight of its collection contractor, should have known that the contractor was making numerous "fatal flaws" in tests. Alternatively, X received a correction notice pointing out these problems in its contractor's collections. In neither case did X take action to correct the problem. X, as well as the contractor, would be subject to a PIE with respect to collections.

Example 6 to §40.391. Service Agent Y could not reasonably have known that one of its MROs was regularly failing to interview employees before verifying tests positive. When it received a correction notice, Y immediately dismissed the erring MRO. In this case, the MRO would be subject to a PIE but Y would not.

Example 7 to §40.391. The Department issues a PIE with respect to Service Agent Z. Z provides services for DOT-regulated transportation employers, a Federal agency under the HHS-regulated Federal employee testing program, and various private businesses and public agencies that DOT does not regulate. The PIE applies only to the DOT-regulated transportation employers with respect to their DOT-mandated testing, not to the Federal agency or the other public agencies and private businesses. The PIE does not prevent the non-DOT regulated entities from continuing to use Z's services.

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§40.393 How long does a PIE stay in effect?

(a) In the NOPE (see §40.375(b)(5)), the initiating official proposes the duration of the PIE. The duration of the PIE is one of the elements of the proceeding that the service agent may contest (see §40.381(b)) and about which the Director makes a decision (see §40.387(b)(4)).

(b) In deciding upon the duration of the PIE, the Director considers the seriousness of the conduct on which the PIE is based and the continued need to protect employers and employees from the service agent's noncompliance. The Director considers factors such as those listed in §40.389 in making this decision.

(c) The duration of a PIE will be between one and five years, unless the Director reduces its duration under §40.407.

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000 as amended by a second effective date in Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§40.395 Can you settle a PIE proceeding?

At any time before the Director's decision, you and the initiating official can, with the Director's concurrence, settle a PIE proceeding.

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000 as amended by a second effective date in Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§40.397 When does the Director make a PIE decision?

The Director makes his or her decision within 60 days of the date when the record of a PIE proceeding is complete (including any meeting with the Director and any additional fact-finding that is necessary). The Director may extend this period for good cause for additional periods of up to 30 days.

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000 as amended by a second effective date in Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§40.399 How does the Department notify service agents of its decision?

If you are a service agent involved in a PIE proceeding, the Director provides you written notice as soon as he or she makes a PIE decision. The notice includes the following elements:

(a) If the decision is not to issue a PIE, a statement of the reasons for the decision, including findings of fact with respect to any material factual issues that were in dispute.

(b) If the decision is to issue a PIE–

(1) A reference to the NOPE;

(2) A statement of the reasons for the decision, including findings of fact with respect to any material factual issues that were in dispute;

(3) A statement of the scope of the PIE; and

(4) A statement of the duration of the PIE.

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000 as amended by a second effective date in Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§40.401 How does the Department notify employers and the public about a PIE?

(a) The Department maintains a document called the "List of Excluded Drug and Alcohol Service Agents." This document may be found on the Department's web site (http://www.dot.gov/ost/dapc). You may also request a copy of the document from ODAPC.

(b) When the Director issues a PIE, he or she adds to the List the name and address of the service agent, and any other persons or organizations, to whom the PIE applies and information about the scope and duration of the PIE.

(c) When a service agent ceases to be subject to a PIE, the Director removes this information from the List.

(d) The Department also publishes a **Federal Register** notice to inform the public on any occasion on which a service agent is added to or taken off the List.

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000 as amended by a second effective date in Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§40.403 Must a service agent notify its clients when the Department issues a PIE?

(a) As a service agent, if the Department issues a PIE concerning you, you must notify each of your DOT-regulated employer clients, in writing, about the issuance, scope, duration, and effect of the PIE. You may meet this requirement by sending a copy of the Director's PIE decision or by a separate notice. You must send this notice to each client within three working days of receiving from the Department the notice provided for in §40.399(b).

(b) As part of the notice you send under paragraph (a) of this section, you must offer to 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.

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000 as amended by a second effective date in Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§40.405 May the Federal courts review PIE decisions?

The Director's decision is a final administrative action of the Department. Like all final administrative actions of Federal agencies, the Director's decision is subject to judicial review under the Administrative Procedure Act (5 U.S.C. 551 *et. seq*).

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000 as amended by a second effective date in Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§40.407 May a service agent ask to have a PIE reduced or terminated?

(a) Yes, as a service agent concerning whom the Department has issued a PIE, you may request that the Director terminate a PIE

or reduce its duration and/or scope. This process is limited to the issues of duration and scope. It is not an appeal or reconsideration of the decision to issue the PIE.

(b) Your request must be in writing and supported with documentation.

(c) You must wait at least nine months from the date on which the Director issued the PIE to make this request.

(d) The initiating official who was the proponent of the PIE may provide information and arguments concerning your request to the Director.

(e) If the Director verifies that the sources of your noncompliance have been eliminated and that all drug or alcohol testing-related services you would provide to DOT-regulated employers will be consistent with the requirements of this part, the Director may issue a notice terminating or reducing the PIE.

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000 as amended by a second effective date in Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§40.409 What does the issuance of a PIE mean to transportation employers?

(a) As an employer, you are deemed to have notice of the issuance of a PIE when it appears on the List mentioned in §40.401(a) or the notice of the PIE appears in the **Federal Register** as provided in §40.401(d). You should check this List to ensure that any service agents you are using or planning to use are not subject to a PIE.

(b) As an employer who is using a service agent concerning whom a PIE is issued, you must stop using the services of the service agent no later than 90 days after the Department has published the decision in the **Federal Register** or posted it on its web site. You may apply to the ODAPC Director for an extension of 30 days if you demonstrate that you cannot find a substitute service agent within 90 days.

(c) Except during the period provided in paragraph (b) of this section, you must not, as an employer, use the services of a service agent that are covered by a PIE that the Director has issued under this subpart. If you do so, you are in violation of the Department's regulations and subject to applicable DOT agency sanctions (*e.g.*, civil penalties, withholding of Federal financial assistance).

(d) You also must not obtain drug or alcohol testing services through a contractor or affiliate of the service agent to whom the PIE applies.

Example to Paragraph (d): Service Agent R was subject to a PIE with respect to SAP services. As an employer, not only must you not use R's own SAP services, but you also must not use SAP services you arrange through R, such as services provided by a subcontractor or affiliate of R or a person or organization that receives financial gain from its relationship with R.

(e) This section's prohibition on using the services of a service agent concerning which the Director has issued a PIE applies to employers in all industries subject to DOT drug and alcohol testing regulations.

Example to Paragraph (e): The initiating official for a PIE was the FAA drug and alcohol program manager, and the conduct forming the basis of the PIE pertained to the aviation industry. As a motor carrier, transit authority, pipeline, railroad, or maritime employer, you are also prohibited from using the services of the service agent involved in connection with the DOT drug and alcohol testing program.

(f) The issuance of a PIE does not result in the cancellation of drug or alcohol tests conducted using the service agent involved before the issuance of the Director's decision or up to 90 days following its publication in the **Federal Register** or posting on the Department's web site, unless otherwise specified in the Director's PIE decision or the Director grants an extension as provided in paragraph (b) of this section.

Example to Paragraph (f): The Department issues a PIE concerning Service Agent N on September 1. All tests conducted using N's services before September 1, and through November 30, are valid for all purposes under DOT drug and alcohol testing regulations, assuming they meet all other regulatory requirements.

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000 as amended by a second effective date in Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§40.411 What is the role of the DOT Inspector General's office?

(a) Any person may bring concerns about waste, fraud, or abuse on the part of a service agent to the attention of the DOT Office of Inspector General.

(b) In appropriate cases, the Office of Inspector General may pursue criminal or civil remedies against a service agent.

(c) The Office of Inspector General may provide factual information to other DOT officials for use in a PIE proceeding.

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000 as amended by a second effective date in Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

§40.413 How are notices sent to service agents?

(a) If you are a service agent, DOT sends notices to you, including correction notices, notices of proposed exclusion, decision notices, and other notices, in any of the ways mentioned in paragraph (b) or (c) of this section.

(b) DOT may send a notice to you, your identified counsel, your agent for service of process, or any of your partners, officers, directors, owners, or joint venturers to the last known street address, fax number, or e-mail address. DOT deems the notice to have been received by you if sent to any of these persons.

(c) DOT considers notices to be received by you–

(1) When delivered, if DOT mails the notice to the last known street address, or five days after we send it if the letter is undeliverable;

(2) When sent, if DOT sends the notice by fax or five days after we send it if the fax is undeliverable; or

(3) When delivered, if DOT sends the notice by e-mail or five days after DOT sends it if the e-mail is undeliverable.

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000 as amended by a second effective date in Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

Appendix A to Part 40–DOT Standards for Urine Collection Kits

The Collection Kit Contents

1. *Collection Container*

a. Single-use container, made of plastic, large enough to easily catch and hold at least 55 mL of urine voided from the body.

b. Must have graduated volume markings clearly noting levels of 45 mL and above.

c. Must have a temperature strip providing graduated temperature readings 32-38 °C/90-100 °F, that is affixed or can be affixed at a proper level on the outside of the collection container. Other methodologies (*e.g.*, temperature device built into the wall of the container) are acceptable provided the temperature measurement is accurate and such that there is no potential for contamination of the specimen.

d. Must be individually wrapped in a sealed plastic bag or shrink wrapping; or must have a peelable, sealed lid or other easily visible tamper-evident system.

e. May be made available separately at collection sites to address shy bladder situations when several voids may be required to complete the testing process.

2. *Plastic Specimen Bottles*

a. Each bottle must be large enough to hold at least 35 mL; or alternatively, they may be two distinct sizes of specimen bottles provided that the bottle designed to hold the primary specimen holds at least 35 mL of urine and the bottle designed to hold the split specimen holds at least 20 mL.

b. Must have screw-on or snap-on caps that prevent seepage of the urine from the bottles during shipment.

c. Must have markings clearly indicating the appropriate levels (30 mL for the primary specimen and 15 mL for the split) of urine that must be poured into the bottles.

d. Must be designed so that the required tamper-evident bottle seals made available on the CCF fit with no damage to the seal when the employee initials it nor with the chance that the seal overlap would conceal printed information.

e. Must be wrapped (with caps) together in a sealed plastic bag or shrink wrapping separate from the collection container; or must be wrapped (with cap) individually in sealed plastic bags or shrink wrapping; or must have peelable, sealed lid or other easily visible tamper-evident system.

f. Plastic material must be leach resistant.

3. Leak-Resistant Plastic Bag

a. Must have two sealable compartments or pouches which are leak-resistant; one large enough to hold two specimen bottles and the other large enough to hold the CCF paperwork.

b. The sealing methodology must be such that once the compartments are sealed, any tampering or attempts to open either compartment will be evident.

4. *Absorbent material*

Each kit must contain enough absorbent material to absorb the entire contents of both specimen bottles. Absorbent material must be designed to fit inside the leak-resistant plastic bag pouch into which the specimen bottles are placed.

5. *Shipping Container*

a. Must be designed to adequately protect the specimen bottles from shipment damage in the transport of specimens from the collection site to the laboratory (*e.g.*, standard courier box, small cardboard box, plastic container).

b. May be made available separately at collection sites rather than being part of an actual kit sent to collection sites.

c. A shipping container is not necessary if a laboratory courier hand-delivers the specimen bottles in the plastic leak-proof bags from the collection site to the laboratory.

[53 FR 47002, Nov. 21, 1988 as amended by Amdt. 40-1, 54 FR 49854, Dec. 1, 1989; Amdt. 40-2, 59 FR 7340, Feb. 15, 1994; Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

Appendix B to Part 40–DOT Drug Testing Semi-Annual Laboratory Report

The following items are required on each report:

Reporting Period: (inclusive dates)
Laboratory Identification: (name and address)
Employer Identification: (name; may include billing code or ID code)
C/C/TPA Identification: (where applicable; name and address)
1. Number of specimen results reported: (total number)

By test type:

(a) Pre-employment testing: (number)
(b) Post-accident testing: (number)
(c) Random testing: (number)
(d) Reasonable suspicion/cause testing: (number)
(e) Return-to-duty testing: (number)
(f) Follow-up testing: (number)
(g) Type not noted on CCF: (number)

2. Number of specimens reported as
(a) Negative: (total number)
(b) Negative-dilute: (number)

3. Number of specimens reported as Rejected for Testing: (total number)
By reason:
(a) Fatal flaw: (number)
(b) Uncorrected flaw: (number)

4. Number of specimens reported as Positive: (total number)

By drug:
(a) Marijuana Metabolite: (number)
(b) Cocaine Metabolite: (number)
(c) Opiates:
(1) Codeine: (number)
(2) Morphine: (number)
(3) 6-AM: (number)
(d) Phencyclidine: (number)
(e) Amphetamines: (number)
(1) Amphetamine: (number)
(2) Methamphetamine: (number):
5. Adulterated: (number)
6. Substituted: (number)
7. Invalid results: (number)

[53 FR 47002, Nov. 21, 1988 as amended by Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

Appendix C to Part 40–[Reserved]

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

Appendix D to Part 40–Report Format: Split Specimen Failure to Reconfirm

Fax or mail to: Department of Transportation, Office of Drug and Alcohol Policy and Compliance, 400 7th Street, SW., Room 10403, Washington, DC 20590 (fax) 202-366-3897.

1. MRO name, address, phone number, and fax number.
2. Collection site name, address, and phone number.
3. Date of collection.
4. Specimen I.D. number.
5. Laboratory accession number.
6. Primary specimen laboratory name, address, and phone number.
7. Date result reported or certified by primary laboratory.
8. Split specimen laboratory name, address, and phone number.
9. Date split specimen result reported or certified by split specimen laboratory.
10. Primary specimen results (*e.g.*, name of drug, adulterant) in the primary specimen.
11. Reason for split specimen failure-to-reconfirm result (*e.g.*, drug or adulterant not present, specimen invalid, split not collected, insufficient volume).
12. Actions taken by the MRO (*e.g.*, notified employer of failure to reconfirm and requirement for recollection).
13. Additional information explaining the reason for cancellation.
14. Name of individual submitting the report (if not the MRO).

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

Appendix E to Part 40–SAP Equivalency Requirements for Certification Organizations

1. *Experience:* Minimum requirements are for three years of full-time supervised experience or 6,000 hours of supervised experience as an alcoholism and/or drug abuse counselor. The supervision must be provided by a licensed or certified practitioner. Supervised experience is important if the individual is to be considered a professional in the field of alcohol and drug abuse evaluation and counseling.

2. *Education:* There exists a requirement of 270 contact hours of education and training in alcoholism and/or drug abuse or related training. These hours can take the form of formal education, in-service training, and professional development courses. Part of any professional counselor's development is participation in formal and non-formal education opportunities within the field.

3. *Continuing Education:* The certified counselor must receive at least 40-60 hours of continuing education units (CEU) during each two year period. These CEUs are important to the counselor's keeping abreast of changes and improvements in the field.

4. *Testing:* A passing score on a national test is a requirement. The test must accurately measure the application of the knowledge, skills, and abilities possessed by the counselor.

The test establishes a national standard that must be met to practice.

5. *Testing Validity:* The certification examination must be reviewed by an independent authority for validity (examination reliability and relationship to the knowledge, skills, and abilities required by the counseling field). The reliability of the exam is paramount if counselor attributes are to be accurately measured. The examination passing score point must be placed at an appropriate minimal level score as gauged by statistically reliable methodology.

6. *Measurable Knowledge Base:* The certification process must be based upon measurable knowledge possessed by the applicant and verified through collateral data and testing. That level of knowledge must be of sufficient quantity to ensure a high quality of SAP evaluation and referral services.

7. *Measurable Skills Base:* The certification process must be based upon measurable skills possessed by the applicant and verified through collateral data and testing. That level of skills must be of sufficient quality to ensure a high quality of SAP evaluation and referral services.

8. *Quality Assurance Plan:* The certification agency must ensure that a means exists to determine that applicant records are verified as being true by the certification staff. This is an important check to ensure that true information is being accepted by the certifying agency.

9. *Code of Ethics:* Certified counselors must pledge to adhere to an ethical standard for practice. It must be understood that code violations could result in de-certification. These standards are vital in maintaining the integrity of practitioners. High ethical standards are required to ensure quality of client care and confidentiality of client information as well as to guard against inappropriate referral practices.

10. *Re-certification Program:* Certification is not just a one-time event. It is a continuing privilege with continuing requirements. Among these are continuing education, continuing state certification, and concomitant adherence to the code of ethics. Re-certification serves as a protector of client interests by removing poor performers from the certified practice.

11. *Fifty State Coverage:* Certification must be available to qualified counselors in all 50 states and, therefore, the test must be available to qualified applicants in all 50 states. Because many companies are multi-state operators, consistency in SAP evaluation quality and opportunities is paramount. The test need not be given in all 50 states but should be accessible to candidates from all states.

12. *National Commission for Certifying Agencies (NCCA) Accreditation:* Having NCCA accreditation is a means of demonstrating to the Department of Transportation that your certification has been reviewed by a panel of impartial experts that have determined that your examination(s) has met stringent and appropriate testing standards.

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

Appendix F to Part 40–Drug and Alcohol Testing Information that C/TPAs May Transmit to Employers

1. If you are a C/TPA, you may, acting as an intermediary, transmit the information in the following sections of this part to the DER for an employer, if the employer chooses to have you do so. These are the only items that you are permitted to transmit to the employer as an intermediary. The use of C/TPA intermediaries is prohibited in all other cases, such as transmission of laboratory drug test results to MROs, the transmission of medical information from MROs to employers, the transmission of SAP reports to employers, the transmission of positive alcohol test results, and the transmission of medical information from MROs to employers.

2. In every case, you must ensure that, in transmitting the information, you meet all requirements (*e.g.*, concerning confidentiality and timing) that would apply if the party originating the information (*e.g.*, an MRO or collector) sent the information directly to the employer. For example, if you transmit MROs'

drug testing results to DERs, you must transmit each drug test result to the DER in compliance with the requirements for MROs set forth in §40.167.

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

Drug Testing Information

§40.25: Previous two years' test results
§40.35: Notice to collectors of contact information for DER
§40.61(a): Notification to DER that an employee is a "no show" for a drug test
§40.63(e): Notification to DER of a collection under direct observation
§40.65(b)(6) and (7) and (c)(2) and (3): Notification to DER of a refusal to provide a specimen or an insufficient specimen
§40.73(a)(9): Transmission of CCF copies to DER (However, MRO copy of CCF must be sent by collector directly to the MRO, not through the C/TPA.)
§40.111(a): Transmission of laboratory statistical report to employer
§40.129 (d): Report of test results to DER
§40.129(f)(1): Report to DER of confirmed positive test in stand-down situation
§40.149(b): Report to DER of changed test result
§40.155(a): Report to DER of dilute specimen
Secs. 40.159(a)(4)(ii); 40.161(b): Reports to DER that test is cancelled
§40.167(b) and (c): Reports of test results to DER
§40.187(a), (b)(1), (c)(1), (d)(1) and (2): Reports to DER concerning the reconfirmation of tests
§40.191(d): Notice to DER concerning refusals to test
§40.193(b)(3): Notification to DER of refusal in shy bladder situation
§40.193(b)(4): Notification to DER of insufficient specimen
§40.193(b)(5): Transmission of CCF copies to DER (not to MRO)
§40.199: Report to DER of cancelled test and direction to DER for additional collection
§40.201: Report to DER of cancelled test

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

Alcohol Testing Information

§40.215: Notice to BATs and STTs of contact information for DER
§40.241(b)(1): Notification to DER that an employee is a "no show" for an alcohol test
§40.247(a)(2): Transmission of alcohol screening test results only when the test result is less than 0.02
§40.255(a)(4): Transmission of alcohol confirmation test results only when the test result is less than 0.02
§40.263(a)(3) and 263(b)(3): Notification of insufficient saliva and failure to provide sufficient amount of breath

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

Appendix G to Part 40–Alcohol Testing Form

The following form is the alcohol testing form required for use in the DOT alcohol testing program beginning August 1, 2001. Use of the form is authorized beginning January 18, 2001.

[Amdt. 40-10, 65 FR 79462, Dec. 19, 2000]

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

STEP 1: TO BE COMPLETED BY ALCOHOL TECHNICIAN

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

B. SSN or Employee ID No. _____

C. Employer Name _____
Street _____
City, ST ZIP _____

DER Name and Telephone No. _____ ( )
DER Name DER Phone Number

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

Affix Or Print Screening Results Here

Affix With Taper Evident Tape

STEP 2: TO BE COMPLETED BY EMPLOYEE

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

_____ / / ____
Signature of Employee Date Month Day Year

Affix Or Print Confirmation Result Here

STEP 3: TO BE COMPLETED BY BREATH ALCOHOL TECHNICIAN

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

TECHNICIAN: ☐ BAT ☐ STT DEVICE: ☐ SALIVA ☐ BREATH* 15-Minute Wait: ☐ Yes ☐ No

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

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

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

Affix With Taper Evident Tape

REMARKS:

Affix Or Print Additional Results Here

_____ _____
Alcohol Technician's Company Company Street Address

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

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

STEP 4: TO BE COMPLETED BY EMPLOYEE

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

_____ _____ / /
Signature of Employee Date Month Day Year

Affix With Taper Evident Tape

COPY 1 – ORIGINAL – FORWARD TO EMPLOYER

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

STEP 1: TO BE COMPLETED BY ALCOHOL TECHNICIAN

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

B. SSN or Employee ID No. _____

C. Employer Name _____
Street _____
City, ST ZIP _____

DER Name and Telephone No. _____ ( ) _____
DER Name DER Phone Number

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

Affix Or Print Screening Results Here

Affix With Taper Evident Tape

STEP 2: TO BE COMPLETED BY EMPLOYEE

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

_____ _____ / /
Signature of Employee Date Month Day Year

Affix Or Print Confirmation Result Here

Affix With Taper Evident Tape

STEP 3: TO BE COMPLETED BY BREATH ALCOHOL TECHNICIAN

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

TECHNICIAN: ☐ BAT ☐ STT DEVICE: ☐ SALIVA ☐ BREATH* 15-Minute Wait: ☐ Yes ☐ No

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

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

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

REMARKS:

_____ _____
Alcohol Technician's Company Company Street Address

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

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

Affix Or Print Additional Results Here

Affix With Taper Evident Tape

STEP 4: TO BE COMPLETED BY EMPLOYEE

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

_____ _____ / /
Signature of Employee Date Month Day Year

COPY 2 – EMPLOYEE RETAINS

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

STEP 1: TO BE COMPLETED BY ALCOHOL TECHNICIAN

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

B. SSN or Employee ID No. _____

C. Employer Name _____
Street _____
City, ST ZIP _____

DER Name and Telephone No. _____ ( ) _____
DER Name DER Phone Number

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

Affix Or Print Screening Results Here

Affix With Taper Evident Tape

STEP 2: TO BE COMPLETED BY EMPLOYEE

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

_____ _____ / /
Signature of Employee Date Month Day Year

Affix Or Print Confirmation Result Here

STEP 3: TO BE COMPLETED BY BREATH ALCOHOL TECHNICIAN

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

TECHNICIAN: ☐ BAT ☐ STT DEVICE: ☐ SALIVA ☐ BREATH* 15-Minute Wait: ☐ Yes ☐ No

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

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

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

Affix With Taper Evident Tape

REMARKS:

Affix Or Print Additional Results Here

_____ _____
Alcohol Technician's Company Company Street Address

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

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

Affix With Taper Evident Tape

STEP 4: TO BE COMPLETED BY EMPLOYEE

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

_____ _____ / /
Signature of Employee Date Month Day Year

COPY 3 – ALCOHOL TECHNICIAN RETAINS

PAPERWORK REDUCTION ACT (as required by 5 CFR 1320.21)

Public reporting burden for this collection of information is estimat ed for each respondent to average: 1 minute/employee, 4 minutes/Breath Alcohol Technician. Individuals may send comments regarding these burden estimates, or any other aspect of this collection of information, including suggestions for reducing the burden, to U.S. Department of Transportation, Drug and Alcohol Policy and Compliance, Room 10403, 400 Seventh St., SW, Washington, D.C. 20590 or Office of Management and Budget, Paperwork Reduction Project, Room 3001, 725 Seventeenth St., NW, Washington, D.C. 20503.

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INSTRUCTIONS FOR COMPLETING THE U.S. DEPARTMENT OF TRANSPORTATION ALCOHOL TESTING FORM

NOTE: Use a ball-point pen, press hard, and check all copies for legibility.

STEP 1 The Breath Alcohol Technician (BAT) or Screening Test Technician (STT) completes the information required in this step. Be sure to print the employee's name and check the box identifying the reason for the test.

NOTE: If the employee refuses to provide SSN or ID number, be sure to indicate this in the re marks section STEP 3. Proceed with STEP 2.

STEP 2 Instruct the employee to read, sign and date the employee certification statement in STEP 2.

NOTE: If the employee refuses to sign the certification statement, do not proceed with the alcohol test. Contact the designated employer representative.

STEP 3 The BAT or STT completes the information required in this step and checks the type of device (saliva or breath) being used. After conducting the alcohol screening test, do the following (as appropriate):

Enter the information for the screening test (test number, testing device name, testing device serial number or lot number and expiration date, time of test with any device-dependent activation times, and the results), on the front of the AFT. For a breath testing device capable of printing, the information may be part of the printed record.

NOTE: Be sure to enter the result of the test exactly as it is indicated on the breath testing device, e.g., 0.00, 0.02, 0.04, etc.

Affix the printed information in the space provided, in a tamper-evident manner (e.g., tape), or the device may print the results directly on the ATF. If the results of the screening test are less than 0.02, print, sign your name, and enter today's date in the space provided. The test process is complete.

If the results of the screening test are 0.02 or greater, a confirmation test must be administered in accordance with DOT regulations. An EVIDENTIAL BREATH TESTING device that is capable of printing confirmation test information must be used in conducting this test.

After conducting the alcohol confirmation test, affix the printed information in the space provided in a tamper-evident manner (e.g., tape), or the device may print the results directly on the ATF. Print, sign your name, and enter the date in the space provided. Go to STEP 4.

STEP 4 If the employee has a breath alcohol confirmation test result of 0.02 or higher, instruct the employee to read, sign, and date the employee certification statement in STEP 4.

NOTE: If the employee refuses to sign the certification statement in STEP 4, be sure to indicate this in the remarks line in STEP 3.

Immediately notify the DER if the employee has a breath alcohol confirmation test result of 0.02 or higher.

Forward Copy 1 to the Employer. Give Copy 2 to the Employee. Retain Copy 3 for the BAT/STT records..

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