City of Mesa	Anti-Drug Plan
Human Resources Department P. O. Box 1466 Mesa, AZ 85211-1466 www.cityofmesa.org	U.S. Department of Transportation http://www.dot.gov/ost/dapc Federal Motor Carrier Safety Administration http://www.fmcsa.dot.gov Pipeline & Hazardous Materials Safety Administration http://www.phmsa.dot.gov
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I. INTRODUCTION

II. ROLES & RESPONSIBILITIES OF SERVICE AGENTS

III. DRUG TESTING REQUIREMENTS

IV. DRUG TESTS REQUIRED

V. COMPANY REQUIREMENTS UPON RECEIVING VERIFIED TEST RESULTS

VI. EMPLOYEE WHO FAILS OR REFUSES A DRUG TEST

VII. DRUG TESTING LABORATORY

VIII. BLIND PERFORMANCE TEST PROCEDURES

IX. MEDICAL REVIEW OFFICER & THE VERIFICATION PROCESS

X. PROBLEMS IN DRUG TESTS

XI. RETENTION OF SAMPLES AND ADDITIONAL TESTING

XII. EMPLOYEE ASSISTANCE PROGRAM (EAP)

XIII. CONFIDENTIALITY AND RELEASE OF INFORMATION

XIV. RECORDKEEPING PROCEDURES

XV. CONTRACTOR/SUB-CONTRACTOR EMPLOYEES

APPENDICES

I. INTRODUCTION

A. Prohibited Drug Policy

1. The Company has a long standing commitment to maintain the highest standards for employee safety and health and the use of controlled substances is contrary to these high standards.

2. This policy is also to bring the company into compliance with federal law. The purpose of the anti-drug plan is to prevent accidents that result from the use of controlled substances by employees who perform covered functions for operators of certain pipeline facilities and employees who have commercial drivers licenses, thereby reducing fatalities, injuries, and property damage.

3. The presence in the body of prohibited substances is not condoned.

B. Implementation of Anti-Drug Plan

1. The company has implemented the Pipeline and Hazardous Material Safety Administration (PHMSA) & Federal Motor Carrier Safety Administration (FMCSA) Drug & Alcohol Testing Regulations as set forth in 49 CFR Parts 199 & 382 and the Department of Transportation (DOT), Procedures for Transportation Workplace Drug & Alcohol Testing Programs, 49 CFR Part 40. The company shall maintain confidential records of the testing results and chain of custody procedures as required by Parts 199, 382 and 40 of the DOT regulations. The Company has designated the drug program manager as the record-keeping agent for all drug test records. The company shall provide all records, whenever deemed necessary, for inspection by any authorized agency and/or operator.

2. Compliance with DOT Regulations §40.1 - DOT Part 40 regulations provide all parties who conduct drug and alcohol tests required by Department of Transportation agency regulations with information on how to conduct these tests and what procedures to use. DOT Part 40 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.

3. The anti-drug plan herein sets forth the requirements of 49 CFR Parts 199, 382, and 40. Those areas of the plan that appears in bold and underlined print reflects the City of Mesa's independent authority to require additional provisions with regard to the drug testing procedures.

C. Background

1. The catalyst for the anti-drug plan is Title 49 Code of Federal Regulations (CFR) Part 199 which requires pipeline operators subject to 49 CFR Parts 192, 193, and 195, and their contractors, and those employees who have commercial driver's licenses (CDL) subject to 49 CFR Part 382, to be tested for prohibited drugs under the following work related conditions:

   a. Pre-Employment

   b. Post-Accident

   c. Random

   d. Reasonable Cause

   e. Return-to-duty

   f. Follow-Up

2. Title 49 CFR Part 40 specifies procedures that must be followed by the company when conducting drug testing pursuant to regulations issued by agencies of the Department of Transportation.

3. Authoritative Interpretations – The DOT Office of Drug Alcohol Policy & Compliance (ODAPC) and the DOT Office of General Counsel (OGC) provide written interpretations of the provisions of 49 CFR Part 40. 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.

D. Definitions – For purposes of this anti-drug plan the following definitions apply:

1. Accident (as defined by the Pipeline and Hazardous Material Safety Administration [PHMSA]) – an incident reportable under Part 191 involving gas pipeline facilities or LNG facilities or an accident reportable under Part 195 involving hazardous liquid pipeline facilities.

   a. §191.3 – An accident on a gas pipeline or LNG facility is defined as an "incident," as follows:

      (1) An event that involves a release of gas from a pipeline or of liquefied natural gas or gas from an LNG facility and:

         a) A death, or personal injury necessitating inpatient hospitalization; or

         b) Estimated property damage, including cost of gas lost, to the operator or others, or both, of $50,000 or more ($5,000 or more for intrastate operators/contractors in Kansas and New Mexico).

      (2) An event that results in an emergency shutdown of an LNG facility.

      (3) An event that is significant, in the judgment of the operator, even though it did not meet the criteria of paragraphs (1) or (2).

   b. §195.50 – An accident report is required for each failure in a pipeline system in which there is a release of the hazardous liquid or carbon dioxide transported resulting in any of the following:

      (1) Explosion or fire not intentionally set by the operator.

      (2) Loss of 50 or more barrels of hazardous liquid or carbon dioxide.

      (3) Escape to the atmosphere of more than five barrels a day of highly volatile liquids.

      (4) Death of any person.

      (5) Bodily harm to any person resulting in one or more of the following:

         a) Loss of consciousness.

         b) Necessity to carry the person from the scene.

         c) Necessity for medical treatment.

         d) Disability that prevents the discharge of normal duties or the pursuit of normal activities beyond the day of the accident.

      (6) Estimated property damage, including cost of clean-up and recovery, value of lost product, and damage to the property of the operator or others, or both, exceeding $50,000.

2. 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.

3. 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 49 CFR Part 40, Subpart F.

4. Blind Sample 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 employee specimens.

5. 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.

6. Chain-of-Custody – procedures to account for the integrity of each urine specimen by tracking its handling and storage from point of specimen collection to final disposition of the specimen. These procedures shall require that an appropriate drug testing custody form from a Department of Health & Human Services (DHHS) certified laboratory be used from time of collection to receipt by the laboratory.

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

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

9. 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.

10. Commerce – any trade, traffic or transportation within the jurisdiction of the United States between a place in a State and a place outside of such State, including a place outside of the United States that affect any trade, traffic and transportation.

11. Commercial motor vehicle – a motor vehicle or combination of motor vehicles used in commerce to transport passengers or property if the vehicle:

    a. Has a gross combination weight rating of 11,794 or more kilograms (26,001 or more pounds) inclusive of a towed unit with a gross vehicle weight rating of more than 4,536 kilograms (10,000 pounds); or

    b. Has a gross vehicle weight rating of 11,794 or more kilograms (26,001 or more pounds); or

    c. Is designed to transport 16 or more passengers, including the driver; or

    d. Is of any size and is used in the transportation of materials found to be hazardous for the purposes of the Hazardous Materials Transportation Act (49 U.S.C. 5103(b) and which require the motor vehicle to be placarded under the Hazardous Materials Regulations (49 CFR Part 172, subpart F).

12. 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.

13. Confirmation (or confirmatory) validity test – a second test performed on a urine specimen to further support a validity test result.

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

15. 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 49 CFR Part 40.
16. 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.

17. Covered employee, employee, or individual to be tested – means any person who performs a covered function, including persons employed by operators, contractors engaged by operators, and persons employed by such contractors.

18. Covered function (safety-sensitive function) – means an operations, maintenance, or emergency-response function regulated by Part 192, 193, or 195 of 49 CFR that is performed on a pipeline or on an LNG facility.

19. DOT procedures – means the Procedures for Transportation Workplace Drug and Alcohol Testing Program published by the Office of the Secretary of Transportation in 49 CFR Part 40.

20. Designated Employer Representative (DER) – an employee authorized by the company to take immediate action(s) to remove employees from safety-sensitive duties, or cause employees to be removed from these covered duties, and to make required decisions in the testing and evaluation processes. The DER also receives test results and other communications for the company, consistent with the requirements of 49 CFR Part 40. Service agents cannot act as DERs.

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

22. Disabling damage – damage that precludes departure of a motor vehicle from the scene of the accident in its usual manner in daylight after simple repairs.

    a. Inclusions. Damage to motor vehicles that could have been driven, but would have been further damaged if so driven.

    b. Exclusions:

        (1) Damage that can be remedied temporarily at the scene of the accident without special tools or parts.

        (2) Tire disablement without other damage even if no spare tire is available.

        (3) Headlight or taillight damage.

        (4) Damage to turn signals, horn, or windshield wipers which make them inoperative.

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

24. DOT procedures – means the Procedures for Transportation Workplace Drug and Alcohol Testing Program published by the Office of the Secretary of Transportation in 49 CFR Part 40.

25. Driver – any person who operates a commercial motor vehicle. This includes, but is not limited to: full time, regularly employed drivers; casual, intermittent or occasional drivers; leased drivers and independent owner-operator contractors.

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

27. 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.

28. 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.

29. 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.

30. Fail a Drug Test or Test Positive – the confirmation test result shows positive evidence of the presence under DOT procedures of a prohibited drug in the employee's or applicant's system.

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

32. Initial drug test. – the test used to differentiate a negative specimen from one that requires further testing for drugs or drug metabolites.

33. Invalid drug test – the result of a drug test for a urine specimen that contains an unidentified adulterant or an unidentified interfering substance, has abnormal physical characteristics, or has an endogenous substance at an abnormal concentration that prevents the laboratory from completing or obtaining a valid drug test result.

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

35. 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 49 CFR Part 40.

36. Licensed medical practitioner – a person who is licensed, certified, and/or registered, in accordance with applicable Federal, State, local, or foreign laws and regulations, to prescribe controlled substances and other drugs.

37. 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.

38. 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.

39. Operator – an owner or operator of pipeline facilities.

40. Performing a covered function – includes actually performing, ready to perform, or immediately available to perform a covered function.

41. Pipeline – all parts of the physical facilities through which product moves in transportation. This includes pipe, valves, and other appurtenances attached to pipe, compressor units, metering stations, delivery stations, holders, and fabricated assemblies.

42. Pipeline facilities – includes new and existing pipeline, rights-of-way, and any equipment, facility, or building used in the transportation of products.

43. Positive rate – means the number of positive results for random controlled substances tests conducted under this part plus the number of refusals of random controlled substances tests required by this part, divided by the total of random controlled substances tests conducted under this part plus the number of refusals of random tests required by this part.

44. 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.

45. Prohibited drug – means any of the following substances specified in Schedule I or Schedule II of the Controlled Substances Act (21 U.S.C. 812): marijuana, cocaine, opiates, amphetamines, and phencyclidine (PCP).

46. 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).

47. 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).

48. Refusal to Submit, Refuse, or Refuse to take – means behavior consistent with DOT Procedures concerning refusal to take a drug test or refusal to take an alcohol test.

49. SAMHSA – Substance Abuse and Mental Health Services Administration, was formerly National Institute on Drug Abuse, ADAMHA, HHS was established by the DHHS in 1986 to regulate laboratories performing analytical tests (drug tests) on human body fluids for employment purposes in the public sector.

50. Safety-sensitive function – all time from the time a driver begins to work or is required to be in readiness to work until the time he/she is relieved from work and all responsibility for performing work.

51. Secretary – the Secretary of Transportation or the Secretary's designee.

52. 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 49 CFR Parts 199, 382, and Part 40. Service agents are not employers for purposes of 49 CFR Parts 199, 382, and 40.

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

54. 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.

55. 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.

56. 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.

57. 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.

58. Substituted specimen – a specimen with creatinine and specific gravity values that are so diminished that they are not consistent with human urine.

59. 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.

E. Company Responsibilities (§40.11)

1. Drug Program Manager (DPM) or Designated Employer Representative (DER): Appendix A contains the name and phone number of the responsible individual(s).

   The DER or other company designated individual shall be responsible for the preparation of a drug testing anti-drug plan which complies with requirements of the Department of Transportation regulations as set forth in 49 CFR Parts 199, 382, and 40. The DER shall be responsible for providing oversight and evaluation on the plan; providing guidance and counseling; reviewing of all discipline applied under this plan for consistency and conformance to human resources policies and procedures; scheduling random drug testing and return-to-duty testing; maintaining a locked file system on drug testing results; and overseeing the employee assistance program (EAP). The DER will ensure a face-to-face evaluation by an approved SAP for employees who either have received a positive drug test or have refused a drug test as required by DOT. The company shall ensure that all covered employees are aware of the provisions and coverage of the company's anti-drug plan.

2. The company shall be responsible for compliance with all applicable requirements and procedures of 49 CFR Part 40.

3. The company is responsible for all actions of its officials, representatives, and agents (including service agents) in carrying out the requirements of the DOT agency regulations.

4. 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 49 CFR Part 40 and DOT agency drug and alcohol testing regulations. Compliance with these provisions is a material term of all such agreements and arrangements.

5. Supervisors: Company individuals responsible for observing the performance and behavior of employees; observation/documentation of events suggestive of reasonable cause; responsible for requests of second supervisor for substantiation and concurrence for reasonable cause testing, if applicable.

6. Employees: Each employee has the responsibility to be knowledgeable of the requirements of the company's anti-drug plan and to fully comply with the provisions of the plan.

F. DOT Testing versus Non-DOT Testing Provisions (§40.13)

1. DOT tests must be completely separate from non-DOT tests in all respects.

2. DOT tests must take priority and must be conducted and completed before a non-DOT test is begun. Any excess urine left over from a DOT test must be discarded and a separate void collected for subsequent non-DOT test.

3. Except as provided in paragraph 4 of this section, the company must not perform any tests on DOT urine or breath specimens other than those specifically authorized by 49 CFR Part 40 or DOT agency regulations. The company 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.

4. The single exception to paragraph 3 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.

5. No one is permitted to change or disregard the results of DOT tests based on the results of non-DOT tests. The company must not disregard a verified positive 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.

6. The company 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. The company must always use the CCF and ATF for all DOT-mandated drug and alcohol tests.

G. Company's Use of Service Agent to Meet DOT Drug & Alcohol Testing Requirements (§40.15)

1. The company may use a service agent to perform the tasks needed to comply with 49 CFR Part 40 and DOT agency drug and alcohol testing regulations, consistent with the requirements of Roles and Responsibilities of Service Agents Section in this plan and other applicable provisions of 49 CFR Part 40.

2. The company is responsible for ensuring that the service agents used meet the qualifications set forth in 49 CFR Part 40 (e.g., Medical Review Officer requirements §40.121). The company may require service agents to show documentation that they meet the requirements of 49 CFR Part 40 (e.g., documentation of MRO qualifications as required in this plan).

3. The company remains responsible for compliance with all applicable requirements of 49 CFR Part 40 and other DOT drug and alcohol testing regulations, even when using a service agent. If the company violates any part of this plan or other DOT drug and alcohol testing regulations because a service agent has not provided services as 49 CFR Part 40 requires, a DOT agency can subject the company to sanctions. The company's good faith use of a service agent is not a defense in an enforcement action initiated by a DOT agency in which the company's alleged noncompliance with 49 CFR Part 40 or a DOT agency drug and alcohol regulation may have resulted from the service agent's conduct.

   a. The company must not permit a service agent to act as the company's Designated Employer Representative (DER).

H. Company's Responsibility For Obtaining Information From Its Service Agents (§40.17)

The company is responsible for obtaining information required by 49 CFR Part 40 from the company's service agents. This is required whether or not the company chooses to use a consortium/third party administrator (C/TPA) as an intermediary in transmitting information to the company. An example of this requirement would be an applicant for a safety-sensitive job takes a pre-employment drug test, but there is a significant delay in the company's receipt of the test result from an MRO or C/TPA. The company must not assume that "no news is good news" and permit the applicant to perform safety-sensitive duties before receiving the result. The company would be in violation of the DOT regulations.

I. Drug and Alcohol Testing Information C/TPAs May Transmit to the Company.

1. The C/TPA may, acting as an intermediary, transmit the information in the following sections of 49 CFR Part 40 to the DER for the company, if the company chooses to do so. These are the only items that the C/TPA is permitted to transmit to the company 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 the company, the transmission of SAP reports to the company, the transmission of positive alcohol test results, and the transmission of medical information from MROs to the company.

2. In every case, the C/TPA must ensure that, in transmitting the information, the C/TPA meets 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 company. For example, if the C/TPA transmitted MROs' drug testing results to DERs, the C/TPA must transmit each drug test result to the DER in compliance with the requirements for MROs set forth in §40.167.

3. 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 when test result is less than 0.02
   §40.255(a)(4):Transmission of alcohol confirmation test results when 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

J. Company use of Consent Form (§40.27)

The company may not require an employee to sign any consent and/or release in connection with the DOT drug and alcohol-testing program. The company 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 49 CFR Part 40 (including, but not limited to, collections, laboratory testing, MRO, and SAP services).

II. ROLES AND RESPONSIBILITIES OF SERVICE AGENTS

A. General Provisions for Service Agents

1. Service agent's compliance with DOT drug and alcohol testing requirements (§40.341).

   a. The service agent who provides services to transportation companies must meet the requirements of 49 CFR Part 40 and the DOT agency drug and alcohol testing regulations.

   b. If the service agent does not comply, DOT may take action under the Public Interest Exclusions procedures of 49 CFR part 40 (see Subpart R) or applicable provisions of other DOT agency regulations.

B. Tasks and Functions of Service Agents.

1. Tasks that a service agent may perform for the company (§40.343) – The service agent may perform for the company the tasks needed to comply with DOT agency drug and alcohol testing regulations, subject to the requirements and limitations of this part.
2. Circumstances in which a C/TPA may act as an intermediary in the transmission of drug and alcohol testing information to the company (§40.345).

   a. The C/TPA or other service agent, may act as an intermediary in the transmission of drug and alcohol testing information in the circumstances specified in this section only if the company chooses to have you do so. Each company makes the decision about whether to receive some or all of this information from the C/TPA, 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 the C/TPA may act as an intermediary are listed in Appendix F to 49 CFR Part 40. These are the only situations in which the C/TPA may act as an intermediary. The C/TPA is prohibited from doing so in all other situations.

   c. In every case, the C/TPA must ensure that, in transmitting information to the company, the C/TPA meets 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 company. For example, if the C/TPA transmits drug-testing results from MROs to DERs, the C/TPA must transmit each drug test result to the DER in compliance with the MRO requirements set forth in §40.167.
3. Functions that C/TPA may perform with respect to administering testing (§40.347) -The C/TPA, except as otherwise specified in this part may perform the following functions for the company concerning random selection and other selections for testing.

   a. The C/TPA 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. The C/TPA 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 the C/TPA combines employees from more than one transportation industry, the C/TPA 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. The C/TPA may assist employers in ensuring that follow-up testing is conducted in accordance with the plan established by the SAP. However, neither the C/TPA nor the employers are permitted to randomly select employees from a '' follow-up pool'' for follow-up testing.

C. Recordkeeping Requirements for Service Agents.

1. Records that a service agent may receive and maintain (§40.349).

   a. Except where otherwise specified in this part, a service agent may receive and maintain all records concerning DOT drug and alcohol testing programs, including positive, negative, and refusal to test individual test results. The service agent does not need the employee's consent to receive and maintain these records.

   b. The C/TPA 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 the company of selected employees) on behalf of the company.

   c. 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 the C/TPA or other service agent who maintains this information for the company.

   d. If the C/TPA is serving as an intermediary, in transmitting information that is required to be provided to the company, the C/TPA must ensure that it reaches the company in the same time periods required elsewhere in this part.

   e. The C/TPA must ensure that he/she can make available to the company within two days any information the company is asked to produce by a DOT agency representative.

   f. At the request of the company, the C/TPA must, at any time on the request of an employer, transfer immediately all records pertaining to the company and its employees to the company or to any other service agent the company designates. The C/TPA must carry out this transfer as soon as the company requests it. The C/TPA is not required to obtain employee consent for this transfer. The C/TPA must not charge more than a reasonable administrative costs for conducting this transfer. The C/TPA may not charge a fee for the release of these records.

   g. If the C/TPA is planning to go out of business or the organization will be bought by or merged with another organization, the C/TPA 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. The C/TPA must carry out this transfer as soon as the employer requests it. The C/TPA is not required to obtain employee consent for this transfer. The C/TPA must not charge more than a reasonable administrative costs for conducting this transfer. The C/TPA may not charge a fee for the release of these records.

D. Confidentiality Requirements for Service Agents.

1. Confidentiality requirements that apply to service agents (§40.351) – Except where otherwise specified in 49 CFR Part 40 the confidentiality requirements apply to the C/TPA and shall include the following:

   a. When the C/TPA receives or maintains confidential information about employees (e. g., individual test results), the C/TPA must follow the same confidentiality regulations as the company with respect to the use and release of this information.

   b. The C/TPA must follow all confidentiality and records retention requirements applicable to the company.

   c. The C/TPA may not provide individual test results or other confidential information to another employer without a specific, written consent from the employee. For example, suppose 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. The C/TPA may not inform Y of the result of a test conducted for X without having a specific, written consent from Jones. Likewise, the C/TPA may not provide this information to employer Z, who is not a C/TPA member, without this consent.

d. The C/TPA must not use blanket consent forms authorizing the release of employee testing information.

e. The C/TPA 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 databases.

2. Principles that govern the interaction between MROs and other service agents (§40.353) – The service agent other than an MRO (e.g., a C/TPA) is subject to the following principles that govern the interaction with MROs:

a. The service agent may provide MRO services to the company, directly or through contract, if the service agent meets all applicable provisions of 49 CFR Part 40.

b. If the service agent employs or contracts for an MRO, the MRO must perform duties independently and confidentially. When the service agent has a relationship with an MRO, the service agent 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.

d. Only the service agent's staff that is 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 the service agent's 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. The service agent must ensure that MRO staff operates under controls sufficient to ensure that the independence and confidentiality of the MRO process are not compromised.

e. Like other MROs, an MRO the service agent employs or contracts with must personally conduct verification interviews with employees and must personally make all verification decisions. Consequently, the service agent staff cannot perform these functions.

E. Service Agent Limitations.

1. Limitations that apply to the activities of service agents (§40.355) – The service agent is subject to the following limitations concerning the service agent's activities in the DOT drug and alcohol-testing program.

a. The service agent must not require an employee to sign a consent, release, waiver of liability, or indemnification agreement with respect to any part of the drug or alcohol testing process covered by this part (including, but not limited to, collections, laboratory testing, MRO, and SAP services). No one may do so on behalf of a service agent.

b. The service agent 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 the service agent with the service agent in turn sending them to the MRO for verification. For example, a practice in which the laboratory transmits results to the service agent's computer system, and the service agent then assign the results to a particular MRO, is not permitted.

c. The service agent must not transmit drug test results directly from the laboratory to the company (by electronic or other means) or to a service agent who forwards them to the company. All confirmed laboratory results must be processed by the MRO before they are released to any other party.

d. The service agent 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 1.f. of this section, the service agent 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 the service agent with you in turn sending them to the actual employer. However, the service agent 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 the service agent simultaneously with sending them to the DER.

f. As an exception to paragraph 1.e. of this section, the service agent 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 1.h. of this section, the service agent 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 company cannot delegate to a C/TPA. The service agent may, however, provide advice and information to the company regarding these testing issues and how the employer should schedule required testing.

h. As an exception to paragraph 1.g. of this section, the service agent 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 1.j. of this section, the service agent must not make a determination that an employee has refused a drug or alcohol test. This is a non-delegable duty of the company. The service agent may, however, provide advice and information to the company regarding refusal-to-test issues.

j. The exception to paragraph 1.i. of this section is that the service agent may make a determination that an employee has refused a drug or alcohol test, if:

(1) The service agent schedules 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) The MRO determines that an individual has refused to test on the basis of adulteration or substitution.

k. The service agent must not act as a DER. For example, while the service agent may be responsible for transmitting information to the company about test results, the service agent must not act on behalf of the company in actions to remove employees from safety-sensitive duties.

l. In transmitting documents to laboratories, the service agent must ensure that the service agent sends to the laboratory that conducts testing only the laboratory copy of the CCF. The service agent is not to transmit other copies of the CCF or any ATFs to the laboratory.

m. The service agent must not impose conditions or requirements on the company that DOT regulations do not authorize. For example, as a C/TPA serving the company in the pipeline or motor carrier industry the service agent must not require the company to have provisions in their DOT plans that PHMSA or FMCSA regulations do not require.

n. The service agent must not intentionally delay the transmission of drug or alcohol testing-related documents concerning actions the service agent has performed, because of a payment dispute or other reasons.

Example 1 to Paragraph (1.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 (1.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 (1.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 (1.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 the service agent must follow the DOT agency regulations, the company remains accountable to DOT for compliance, and the service agent's failure to implement any aspect of the program as required in

this part and other applicable DOT agency regulations makes the company subject to enforcement action by the Department.

III. DRUG TESTING REQUIREMENTS

A. Applicability.

1. Individuals Subject to Drug Testing: Any applicant/employee who would perform on a pipeline, an operating, maintenance, or emergency response function regulated by Part 192, 193, or 195, and who would operate a commercial motor vehicle in commerce in any State regulated by Part 382 would be subject to drug testing under this program. The person may be employed by the operator, be a contractor engaged by the operator, or be employed by such a contractor. The following is a link that will provide a list of employee titles subject to testing under this program: FMCSA and PHMSA DOT Position Listing

2. Procedure for Notifying Employees: This anti-drug-testing plan shall be included in the appropriate company manual. Upon receipt of the company's anti-drug plan, each manager shall post the plan in a prominent location that is readily accessible to all covered employees. All covered employees will be provided a complete copy of the anti-drug plan.

3. Substances for Which Testing Must Be Conducted: The company shall test each employee who performs a function listed in the FMCSA and PHMSA DOT Position Listing for evidence of the following substances:

Marijuana, Cocaine, Opiates, Phencyclidine (PCP), and Amphetamines

B. Background Procedures (§40.25) – A company must check on the drug and alcohol testing record of employees it is intending to use to perform safety-sensitive duties.

1. The company must, after obtaining an employee's written consent, request the information about the employee listed in paragraph 2 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, the company must not permit the employee to perform safety-sensitive functions.

2. The company must request the information listed below from all DOT- regulated companies who have employed the employee for any length of time and up to three (3) years for employees who will be performing safety-sensitive duties under FMCSA regulations or two (2) years for employees who will be performing safety-sensitive duties under PHMSA regulations before the date of the employee's application or transfer.

   a. Alcohol tests with a result of 0.04 or higher alcohol concentration;

   b. Verified positive drug tests;

   c. Refusals to be tested (including verified adulterated or substituted drug test results);

   d. Other violations of DOT agency drug and alcohol testing regulations; and

   e. 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 company does not have information about the return-do-duty process (e.g., a company who did not hire an employee who tested positive on a pre-employment test), the company must seek to obtain this information from the employee.

3. 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.

4. If feasible, the company must obtain and review this information before the employee first performs safety-sensitive functions. If this is not feasible, the company must obtain and review the information as soon as possible. However, the company 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 the company has obtained or made and documented a good faith effort to obtain this information.

5. If the company obtains information that the employee has violated a DOT agency drug and alcohol regulation, the company must not use the employee to perform safety-sensitive functions unless the company also obtain information that the employee has subsequently complied with the return-to-duty requirements of Subpart O of 49 CFR Part 40 and DOT agency drug and alcohol regulations.

6. The company must provide to each of the employers from whom they request information under paragraph 2 of this section written consent for the release of the information cited in paragraph 1 of this section.

7. The release of information under this section must be in any written form (e.g., fax, e-mail, letter) that ensures confidentiality. The previous company 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.

8. The company from whom information is requested under paragraph 2 of this section must, after reviewing the employee's specific, written consent, immediately release the requested information to the company making the inquiry.

9. As the company requesting the information required under this section, the company must maintain a written, confidential record of the information the company obtained or of the good faith efforts the company made to obtain the information. The company must retain this information for three years from the date of the employee's first performance of safety-sensitive duties for the company.

10. The company 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 a company 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 three (3)years. If the employee admits that he or she had a positive test or a refusal to test, the company must not use the employee to perform safety-sensitive functions for the company, until and unless the employee documents successful completion of the return-to-duty process (see paragraphs B.2.e. and B.5. of this section).

IV. Drug Tests Required – The City will require an individual to complete a subsequent drug test should the results of the initial drug test be confirmed by a MRO as “dilute”.

A. Pre-Employment Testing.

1. A pre-employment drug test must be conducted before an individual is hired or contracted and when an individual is transferred/promoted from a non-covered to a covered position. This includes when an individual switches back and forth from a covered position to a non-covered position and back again (i.e. going in and out of the random testing program). This also applies to employees returning from a leave of absence who have not been participating in the anti-drug plan and subject to the random selection process.

2. A negative test result is required prior to allowing an employee to perform any covered functions.

B. Post-Accident Testing.

When a covered employee maintains a CDL and is employed in the pipeline area, the more stringent regulations will apply (FMCSA vs. PHMSA)

If circumstances surrounding an accident do not meet DOT criteria, Supervisors must conduct an observation of the employee to determine if there is reasonable cause to believe the employee’s actions were the result of misusing alcohol and/or abusing controlled substances.

Supervisors will have mandatory training by a Substance Abuse Professional as required by the Department of Transportation federal regulations. In addition, training by DRE-HGN (Drug Recognition Expert – Horizontal Gaze Nystagnamus) certified police officers will be made available to supervisors. Supervisors having a reasonable belief

that a City employee is under the influence following a motor vehicle accident, may request assistance from the Mesa Police Department or Safety Services in determining whether the employee is actually under the influence of alcohol and/or drugs.

1. **PHMSA**: The City, as soon as possible but no later than 32 hours after an accident, shall test each employee for controlled substances whose performance either contributed to the accident or cannot be completely discounted as a contributing factor to the accident. The City's decision not to test must have been based upon the determination, using the best information available immediately after the accident that the employee's performance could not have contributed to the accident or that, because of the time between that performance and the accident, it is not likely that a drug test would reveal whether the performance was affected by drug use. For PHMSA purposes, an accident is defined as an incident reportable under Part 191. In 49 CFR Part 191.3 an incident means an ***event*** that::

    a. Involves a release of gas from a pipeline, or of liquefied natural gas, liquefied petroleum gas, refrigerant gas, or gas from an LNG facility **AND** that results in one or more of the following consequences:

        (1) A death or personal injury resulting in-patient hospitalization; **OR,**

        (2) Estimated property damage of $50,000 or more, including loss to the operator and others, or both, but excluding cost of gas lost; **OR,**

        (3) Unintentional estimated gas loss of three million cubic feet or more.Results in an emergency shutdown of an LNG facility.

    c. Was significant, in the judgment of the City, even though it did not meet the criteria of paragraphs (1) or (2) above.

2. **FMCSA**: The City, as soon as practicable following an occurrence involving a commercial motor vehicle operating on a public road in commerce, shall test for controlled substances for each of its surviving drivers:

    a. Who was performing safety-sensitive functions with respect to the vehicle, if the accident involved the loss of human life; or

    b. Who receives a citation within thirty-two hours of the occurrence under State or local law for a moving traffic violation arising from the accident, if the accident involved:

        (1) Bodily injury to any person who, as a result of the injury, immediately receives medical treatment away from the scene of the accident; or

        (2) One or more motor vehicles incurring disabling damage as a result of the accident, requiring the motor vehicle to be transported away from the scene by a tow truck or other motor vehicle.

3. The appropriate company official must take all reasonable steps to obtain a urine sample from an employee after an accident, as defined in this plan, but any injury should be treated first.

    a. In the case of a conscious but hospitalized employee, management should request that the hospital or medical facility obtain the sample from the employee under DOT drug testing requirements as set forth in 49 CFR Part 40.

    b. If an employee is injured, unconscious (employee is unable to communicate), or otherwise unable to evidence consent (employee is unable to sign custody and control form) to the drug test, all reasonable steps must be taken to obtain a urine sample from the employee.

    c. If an employee is conscious (employee can communicate) and he/she is able to evidence consent (employee able to sign custody and control form) to the drug test and is able to void normally (without aid of catheters) the specimen shall be collected.

    d. If an employee who is subject to post-accident testing is conscious, able to urinate normally (in the opinion

of a medical professional), and refuses to be tested, that employee will be removed from duty and will be subject to disciplinary action up to and including termination.

4. The following steps will be used to guide the supervisor to a satisfactory outcome in a post-accident situation.

   a. Verify the post-accident decision. Does the definition of accident in Section I apply to the current situation. Does the possibility exist that the employee's performance contributed to the accident or cannot be completely discounted as a contributing factor to the accident? Anonymous tips must be taken seriously, but should not be the sole reason to initiate a request for a specimen. If witnesses saw a specific event or behavior, ask them to describe what they saw. How far away were they? Before proceeding further, obtain approval from the department director or designee to proceed with post-accident testing.

   b. Isolate and inform the employee. Remove the employee from the work place. Explain that you have reason to believe their performance contributed to the accident or cannot be completely discounted as a contributing factor to the accident.

   c. Transport the employee. The potentially affected employee will not be allowed to proceed alone to or from the collection site. In addition to the safety concerns for the employee, accompanying the employee also assures that there is no opportunity en route to the collection site for the employee to ingest anything that could affect the test result or to acquire "clean" urine from another person.

   d. Document the events. Record the activity performed that support the determination to conduct a post-accident test. This documentation of the employee's activity should be prepared and signed by the supervisor within 24 hours of the accident or before the results of the tests are released, whichever is earlier, if possible.

   e. Denial should be an expected reaction. If a person knows they will test positive, they may give many explanations and protestations, wanting to avoid drug testing. If they are not under the influence or affected by a prohibited drug, vehement denial also would be expected. Listen to the employee and carefully evaluate the employee's explanation. Remember, a request for urine specimen is not an accusation; it is merely a request for additional objective data. To the employee it may feel like an accusation; so it is important to stress that this is merely a request for additional data.

   f. Following collection. After returning from the collection site, the employee should not be allowed to perform covered functions pending the results of the drug test.

C. Random Testing.

1. The primary purposes of random testing are to deter prohibited drug use and to ensure a drug free workforce. DOT regulations require that covered employees shall be subject to drug testing on an unannounced and random basis. The company shall conduct a number of tests equal to at least 25 percent for PHMSA covered employees and 50 percent for FMCSA covered employees each calendar year, spread reasonably over a 12-month period. Random testing will be conducted monthly.

2. The following is a discussion of the key aspects of the random testing selection process.

   a. Employees remain in the random selection pool at all times, regardless of whether or not they have been previously selected for testing.

   b. Employees shall be selected for testing by using a computer based random number generator or equivalent random selection method that is matched with an employee's social security number or employee ID number.

   c. The process will be unannounced as well as random. Employees will be notified that they have been selected for testing after they have reported for duty on the day of collection.

d. Employees will be selected for random testing based on the number of covered employees at the time and the necessary testing rate.

e. Specimen collection will be conducted on different days of the week throughout the annual cycle to prevent employees from matching their drug use patterns to the schedule for collection.

3. Steps for random testing:

a. The company, on a pre-determined date, shall use the random selection procedures to compile a list of covered employees selected for random testing during that testing cycle.

b. The company shall ensure that the list of social security numbers or employee identification numbers will identify the correct employees who are to be randomly tested during the testing cycle.

c. It is the intent of this plan to notify employees of their selection for random testing after they have reported for duty.

(1) The list of employees to be tested will be generated by the City's DER.

(2) The list of employees who have been selected for random drug testing will be retained by the DER (or designee) in a secure location.

d. The DER will provide the supervisor specific instructions on the testing process such as the location of the collection site, the type of test being conducted (drug testing only versus drug and alcohol testing), the allowable reporting timeframe, etc:

- The collection must occur on that day regardless of their work schedule (meetings, training, etc.)
- If the employee selected for the random is off duty due to an illness, scheduled day off, regular day off, etc., the employee shall be called for testing anytime during the random draw period, but before the next random draw date. If an employee is anticipated to be off for an extended period of time not to return before the next random draw, then the DER shall select the identified alternate employee for testing.
- It is the supervisor's responsibility to notify the employee and ensure the employee makes it to the collection site as required.
    - When necessary, the department may delay notifying the employee to allow for the completion of training sessions, meetings, etc.
    - Once the employee is notified of the requirement to complete random testing, the employee must proceed immediately to the collection site.
    - A "reasonable amount of time" to report for testing at the collection site is defined by the City is 30 minutes plus travel time.
    - Once the employee is in route to the collection site, the employee shall not take any detours or make any stops for soda, coffee, water, etc.
- It is not necessary for supervisors to accompany or escort employees when on-site collection services are being used.
- The employee is required to provide their driver's license or City identification badge for photo I.D.

4. Notification of employees:

a. The appropriate manager/supervisor will notify the employee to be tested to report to the manager/supervisor's office at a specified time.

b. The employee will not be notified of the test until after reporting for duty.

c. Employees shall report immediately to the collection site or to the collection site within 30 minutes, plus travel time, once notified by the appropriate company official.

D. Reasonable Cause Testing. Reasonable cause testing is designed to provide management with a tool (in conjunction with supervisor training on the signs and symptoms of drug use) to identify drug-affected employees who may pose a danger to themselves and others in their job performance. Employees may be at work in a condition that raises concern regarding their safety or productivity. Supervisors must then make a decision as to whether there is reasonable cause to believe an employee is using or has used a prohibited drug.

1. The decision to test must be based on a reasonable and articulate belief that the employee is using a prohibited drug on the basis of specific, contemporaneous physical, behavioral, or performance indicators of probable drug use. The observations may include indications of the chronic and withdrawal effects of substance abuse. At least two of the employee's supervisors, one of whom is trained in detection of the possible symptoms of drug use, shall substantiate and concur in the decision to test an employee. The concurrence by both supervisors can be accomplished by phone or by having another supervisor travel to the job site, if only one supervisor is available at that particular job site.

2. A company with fewer than 50 covered employees need only utilize one supervisor under the reasonable cause determination.

3. In making a determination of reasonable cause, the factors to be considered include, but are not limited to the following:

   a. Adequately documented pattern of unsatisfactory work performance, for which no apparent non-impairment related reason exists, or a change in an employee's prior pattern of work performance, especially where there is some evidence of drug related behavior on or off the work site.

   b. Physical signs and symptoms consistent with substance abuse.

   c. Evidence of illegal substance use, possession, sale, or delivery while on duty.

   d. Occurrence of a serious or potentially serious accident that may have been caused by human error, or flagrant violations of established safety, security, or other operational procedures.

4. The following steps will be used to guide the supervisor to a satisfactory outcome in a reasonable cause situation.

   a. Verify the reasonable cause decision. Anonymous tips must be taken seriously, but should not be the sole reason to initiate a request for a specimen. Hearsay is not an acceptable basis for reasonable cause referral. If witnesses saw a specific event or behavior, ask them to describe what they saw. How far away were they? How long did they observe the person? What, if anything, caused them to believe it was substance abuse related? On what basis did they reach their conclusion? Before proceeding further, obtain approval from the department director or designee to proceed with reasonable cause testing.

   b. Isolate and inform the employee. Remove the employee from the work location. Explain that there is reasonable cause to believe the employee's performance is or has been affected by some substance. Ask the employee to explain the suspected behavior and to describe the events that took place from their perspective. Ask if there is any medication or physical condition that would explain the behavior. A persuasive explanation may or may not deter you from asking for a urine sample. If there is still a reasonable belief that drugs are a factor in the situation/incident, a request for testing should be made; if no reasonable belief is determined then no request for testing should be made. If the decision to test is made, inform the employee that they are being requested to accompany the appropriate official to the specimen collection site to provide a urine specimen. Inform the employee of the consequences of refusal to submit to testing.

   c. Review your findings. During the conversation, observe physical and mental symptoms. Be sure to document any characteristics that either support or contradict initial information. In all cases, a reasonable

cause decision must be made by two of the employee's supervisors. This creates greater objectivity, provides additional observation, and generally strengthens the defensibility of the reasonable cause determination.

d. Transport the employee. The potentially affected employee should not be allowed to proceed alone to or from the collection site. In addition to the safety concerns for the employee, accompanying the employee also assures that there is no opportunity en route to the collection site for the employee to ingest anything that could affect the test result or to acquire "clean" urine from another person.

e. Document the events. Record the behavioral signs and symptoms that support the determination to conduct a reasonable cause test. This documentation of the employee's conduct should be prepared and signed by the witnesses within 24 hours of the observed behavior or before the results of the tests are released, whichever is earlier.

f. Denial should be an expected reaction. If a person knows they will test positive, they may give many explanations and protestations, wanting to avoid drug testing. If they are not under the influence or affected by a prohibited drug, vehement denial also would be expected. Listen to the employee and carefully evaluate the employee's explanation. Remember, a request to provide a urine specimen is not an accusation; it is merely a request for additional objective data. To the employee it may feel like an accusation; so it is important to stress that this is merely a request for additional data.

g. Following collection. After returning from the collection site, the employee shall not perform duties pending the receipt of the drug test results. The employee should make arrangements to be transported home. The employee should be instructed not to drive any motor vehicle due to the reasonable cause belief that they may be under the influence of a drug. If the employee insists on driving, the proper local enforcement authority should be notified that an employee who we believe may be under the influence of a drug is leaving the company premises driving a motor vehicle.

Supervisors will have mandatory training by a Substance Abuse Professional as required by the Department of Transportation federal regulations. In addition, training by DRE-HGN (Drug Recognition Expert – Horizontal Gaze Nystagnamus) certified police officers will be made available to supervisors. Supervisors having a reasonable belief that a City employee is under the influence following a motor vehicle accident, may request assistance from the Mesa Police Department or Safety Services in determining whether the employee is actually under the influence of alcohol and/or drugs.

E. Return-to-Duty Testing.

1. A covered employee who refuses to take or has a positive drug test may not return to duty in a covered function until the covered employee has complied with applicable provisions of DOT Procedures concerning substance abuse professionals and the return-to-duty process.

2. The employee must pass a DOT drug test and the MRO, the SAP and the company must have determined that the employee may return-to-duty. An employee who returns to duty shall be subject to a reasonable program of follow-up drug testing, without prior notice, for up to 60 months after his or her return to duty. The employee may also be required in some circumstances to complete a company mandated rehabilitation program.

3. **Refer to the City of Mesa's Management Policy 316 – Alcohol and Drug Free Workplace for internal policies relating to discipline and the "Last Chance Agreement" requirement. This policy and the appropriate form are accessible through the Intranet under Human Resources Department.**

F. Follow-Up Testing.

1. A covered employee who refuses to take or has a positive drug test will be subject to unannounced follow-up drug tests administered by the company following the covered employee's return to duty. The number and

frequency of such follow-up testing shall be determined by a substance abuse professional, but shall consist of at least six (6) tests in the first twelve (12) months following the covered employee's return to duty.

2. In addition, follow-up testing may include testing for alcohol as directed by the substance abuse professional, to be performed in accordance with 49 CFR Part 40. Follow-up testing shall not exceed 60 months from the date of the covered employee's return to duty.

3. The substance abuse professional may terminate the requirement for follow-up testing at any time after the first six (6) tests have been administered, if the substance abuse professional determines that such testing is no longer necessary.

G. Company Stand Down Procedures (§40.21 & 199.7). The company may stand down an employee before the MRO has completed the verification by following these procedures.

1. The company is prohibited from standing employees down, except consistent with a waiver a DOT agency grants under 49 CFR Part 40.

2. The company may make a request to the concerned DOT agency for a waiver from the prohibition of the above paragraph in this section. Such a waiver, if granted, permits the company 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.

   a. 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.

   b. Before taking action on a waiver request, the concerned DOT agency coordinates with other DOT agencies that regulate the company's other covered employees.

   c. 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.

3. The company request for a waiver must include, as a minimum, the following elements:

   a. Information about the company's organization:

      (1) The company's determination that standing employees down is necessary for safety in the company's organization and a statement of the company's 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;

      (2) Data showing the number of confirmed laboratory positive, adulterated, and substituted test results for the company's 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;

      (3) 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

      (4) A statement of which DOT agencies regulate the company's employees.

   b. The company's proposed written company policy concerning stand-down, which must include the following elements:

      (1) The company's assurance that they will distribute copies of the company's written policy to all employees that it covers;

(2) The company's 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 the company's organization (or subsequently to another company) other than the employee, the MRO and the DER;

(3) The company's means of ensuring that all covered employees in a particular job category in the company's organization are treated the same way with respect to stand-down;

(4) The company's means of ensuring that a covered employee will be subject to stand-down only with respect to the actual performance of safety-sensitive duties;

(5) The company's means of ensuring that the company 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;

(6) The company's 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 the company is informed in writing by the MRO that a longer period is needed to complete the verification process; and

(7) The company's means of ensuring that, in the event that the MRO verifies the test negative or cancels it --

(a) The company returns 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) The company maintains no individually identifiable record that the employee had a confirmed laboratory positive, adulterated, or substituted test result (i.e., the company maintains a record of the test only as a negative or cancelled test).

4. 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 the company's organization, there is a high probability that the procedures the company proposes will effectively enhance safety and protect the interests of employees in fairness and confidentiality.

a. The Administrator, or his or her designee, may impose any conditions he or she deems appropriate on the grant of a waiver.

b. The Administrator, or his or her designee, may immediately suspend or revoke the waiver if he or she determines that the company has failed to protect effectively the interests of employees in fairness and confidentiality, that the company has failed to comply with the requirements of this section, or that the company has failed to comply with any other conditions the DOT agency has attached to the waiver.

5. The company must not stand employees down in the absence of a waiver, or inconsistent with the terms of your waiver. The company shall be in violation of 49 CFR Part 40 and DOT agency drug testing regulations, and the company is subject to enforcement action by the DOT agency just as the company is for other violations of this 49 CFR Part 40 and DOT agency rules.

V. COMPANY REQUIREMENTS UPON RECEIVING VERIFIED TEST RESULTS (§40.23)

A. General.

1. When the company receives a verified positive drug test result, the company must immediately remove the employee involved from performing safety-sensitive functions. The company 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.

2. When the company receives a verified adulterated or substituted drug test result, the company must consider this a refusal to test and immediately remove the employee involved from performing safety-sensitive functions. The company 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.

3. When the company receives an alcohol test result of 0.04 or higher, the company must immediately remove the employee involved from performing safety-sensitive functions. If the company receives an alcohol test result of 0.02 – 0.39, the company 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.

4. When the company receives notification that an employee has a verified positive, adulterated, or substituted test result, or has otherwise violated a DOT agency drug and alcohol regulation, the company 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.

5. When the company receives a drug test result indicating that the employee's specimen was dilute, the company must take action as provided in Section X, paragraph D of this plan (§40.197).

6. When the company receives a drug test result indicating that the employee's specimen was invalid and that a second collection must take place under direct observation –

    a. The company must immediately direct the employee to provide a new specimen under direct observation.

    b. The company must not attach consequences to the finding that the test was invalid other than collecting a new specimen under direct observation.

    c. The company must not give any advance notice of this test requirement to the employee.

    d. The company must instruct the collector to note on the CCF the same reason (e.g. random test, post-accident test) as for the original collection.

7. When the company receives a cancelled test result when a negative result is required (e.g., pre-employment, return-to-duty, or follow-up test), the company must direct the employee to provide another specimen immediately.

8. The company 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).

9. The company must not alter a drug or alcohol test result transmitted to you by an MRO, BAT, or C/TPA.

VI. EMPLOYEE WHO FAILS OR REFUSES A DRUG TEST

A. General. Compliance with this anti-drug testing plan is a condition of employment. Refusal to take a required DOT drug test or failure of a drug test shall result in removal from performing covered functions. Additional disciplinary action up to and including termination may result.

Persons/employees who refuse to take a substance abuse test as prescribed under Personnel Rule Section 550, or who are referred to a substance abuse rehabilitation program and fail to participate in or successfully complete that program, shall either not be hired or used for City work, or if already hired or working on City tasks, shall be separated from the City.

B. Prohibitions On Use. The company shall not use, in a function covered by Parts 199 & 382, anyone who:

1. Fails a drug test as verified by the MRO and the determination is made by the MRO that there is no legitimate medical explanation for the confirmed positive test other than unauthorized use of a prohibited drug, or

2. Refuses to take a drug test required by this plan.

C. Options For Return-To-Duty. An employee will be given an opportunity to retain his or her employment, provided they first:

1. Have been evaluated face-to-face by a SAP, followed any recommendations for drug misuse assistance, if needed,

2. Been considered by the medical review officer in accordance with DOT Procedures and been determined by a substance abuse professional to have successfully completed the required education or treatment, and

3. Pass a DOT drug test, and

4. Not failed a drug test required by Parts 199 & 382 after returning to duty. Such failure will result in removal from performing covered functions and may result in disciplinary action up to and including termination.

VII. DRUG TESTING LABORATORY

A. NIDA Laboratory.

1. The company shall use a drug testing laboratory certified under DHHS Mandatory Guidelines for Federal Workplace Drug Testing Programs; 53 FR 11970, April 11, 1988 and subsequent amendments.

2. The laboratory shall provide services in accordance with Part 40 and Parts 199 & 382. The name and address of each NIDA laboratory used by the company is contained in Appendix A.

3. The laboratory shall permit inspections by the company, the PHMSA or FMCSA Administrator, or if the company is subject to the jurisdiction of a state agency, a representative of the state agency.

B. Laboratory Procedures. These procedures are addressed in Appendix D.

C. Validity Testing Procedures.

1. General – 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.

2. Definition of validity testing and requirements of laboratories authorized to conduct (§40.89).

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. The laboratory is authorized to conduct validity testing.

3. Validity tests that laboratories must conduct on primary specimens (§40.91) - The laboratory conducting validity testing under the authorization of §40.89(b), must conduct it in accordance with the requirements of this section.

a. The laboratory must test each primary specimen for creatinine. The laboratory must also determine its specific gravity if you find that the creatinine concentration is less than 20 mg/dl.

b. The laboratory must measure the pH of each primary specimen.

c. The laboratory must test each primary specimen to determine if it contains substances that may be used to adulterate the specimen. The 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 the laboratory suspect the presence of an interfering substance/adulterant that could make a test result invalid, but the laboratory is unable to identify it (e.g., a new adulterant), the laboratory may, as the first laboratory, send the specimen to another HHS certified laboratory that has the capability of doing so.

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

f. The laboratory must conserve as much as possible of the specimen for possible future testing.

4. Criteria laboratories use to establish that a specimen is dilute or substituted (§40.93).

a. The laboratory 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. The laboratory 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.

5. Criteria laboratories use to establish that a specimen is adulterated (§40.95).

a. The laboratory 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 the determination under paragraph (a) of this section, the laboratory must apply the criteria in current HHS requirements or specimen validity guidance.

6. Laboratory retention of urine specimens after testing (§40.99).

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

b. The laboratory 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 company, 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 the laboratory receives such a request, the laboratory must comply with it. If the laboratory does not receive such a request, the laboratory may discard the specimen at the end of the year.

d. If the laboratory does not send the split specimen to another laboratory for testing, the laboratory must retain the split specimen for an employee's test for the same period of time that the primary specimen is retained and under the same storage conditions.

e. The laboratory testing the split specimen must meet the requirements of paragraphs a –c of this section with respect to the split specimen.

7. Basis for the MRO to verify test results involving adulteration or substitution (§40.131).

a. The MRO, when receiving a laboratory report that a specimen is adulterated or substituted, 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.

b. The MRO must follow the same procedures used for verification of a confirmed positive test for a drug or drug except as otherwise provided in this section.

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

d. The MRO 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 the creatinine and specific gravity criteria of §40.93(b).

(3) The employee must present information meeting this burden at the time of the verification interview. The MRO has the 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. The MRO or the company, is not responsible for arranging, conducting, or paying for any studies, examinations or analyses to determine whether a legitimate medical explanation exists.

g. The MRO must exercise the best professional judgment in deciding whether the employee has established a legitimate medical explanation.

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

(2) If the MRO believes that the employee's explanation may present a reasonable basis for concluding that there is a legitimate medical explanation, the MRO 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.)

(a) The MRO or company is not responsible for finding or paying a referral physician. However, on request of the employee, the company 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 the company.

(b) The MRO 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, the company 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 the MRO with a signed statement of his or her recommendations.

(3) The referral physician must evaluate the employee and consider any evidence the employee presents concerning the employee's medical explanation. The MRO 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) The referral physician 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) The MRO shall determine that there is a legitimate medical explanation and 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) If the MRO 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).

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

(b) 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).

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

(b) 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).

8. Criteria for second laboratory regarding the split specimen when it is tested to reconfirm an adulterated test result (§40.179) - The laboratory testing the split specimen must test the split specimen for the adulterant detected in the primary specimen using the same criteria that were used for the primary specimen or HHS guidance, as applicable. The result of the primary specimen is reconfirmed if the split specimen meets these criteria.

9. Criteria for second laboratory regarding the split specimen when it is tested to reconfirm a substituted test result (§40.181) - The laboratory testing the split specimen must test the split specimen using the criteria of §40.93 (b), just as the laboratory would do for a primary specimen. The result of the primary specimen is reconfirmed if the split specimen meets these criteria.

10. Information that laboratories report to MROs regarding split specimen results (§40.183).

a. The laboratory responsible for testing the split specimen using the Federal Drug Testing Custody and Control Form (CCF) issued by HHS on June 23, 2000, the laboratory must report split specimen test results in adulteration and substitution situations by checking the “Reconfirmed” box or the “Failed to Reconfirm” box (Step 5(b)) on Copy 1 of the CCF.

b. If the laboratory checked 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)/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. If the laboratory is using the CCF issued by HHS prior to June 23, 2000, enter the information referenced in paragraph (b) (2), (3), or (4) of this section on the “remarks” line.

d. Laboratory certifying scientist must enter his/her name, sign, and date the CCF.

11. MRO requirements regarding split specimen laboratory results (§40.187) – The MRO must take the following actions when a laboratory reports the following results of split specimen tests concerning adulterated or substituted specimens:

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.

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) Inform ODAPC of the failure to reconfirm.

c. Failed to Reconfirm: Adulterated or Substituted (as appropriate); Criteria Not Met.

(1) Report to the DER and the employee that both tests must be cancelled.

(2) 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) Inform ODAPC of the failure to reconfirm.

e. Enter your name, sign and date the appropriate copy of the CCF.

f. Send a legible copy of the appropriate copy of the CCF (or a signed and dated letter) to the employer and keep a copy for your records.

VIII. BLIND PERFORMANCE TEST PROCEDURES

A. General.

1. The company shall use blind testing quality control procedures as provided in this section.

B. Covered Employees.

1. The company with an aggregate of 2,000 or more DOT-covered employees must send blind specimens to each laboratory used by the company. If the company has an aggregate of fewer than 2,000 DOT-covered employees the company is not required to provide blind specimens.

2. For each laboratory to which the company sends at least 100 specimens a year, the company must transmit a number of blind specimens equivalent to one percent of the specimens the company sends to that laboratory, up to a maximum of 50 blind specimens in each quarter. The company must apply this percentage to the total number of DOT-covered employees' specimens sent to the laboratory. Blind specimen submissions must be evenly spread throughout the year.

3. Approximately 75 percent of the specimens the company submits must be blank (i.e. containing no drugs, nor adulterated or substituted.) Approximately 15 per cent must be positive for one or more of the five drugs involved in DOT tests, and approximately 10 per cent must either be adulterated with a substance cited in HHS guidance or substituted (i.e., having specific gravity and creatinine meeting the criteria of 49 CFR Part 40.93(b)

a. The blind specimens submitted 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.

b. The supplier must provide information regarding the shelf life of the blinds specimens.

c. 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.

d. 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.

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

f. If the blind specimen is substituted, the creatinine must be less than or equal to 2, and the specific gravity must be 1,000.

4. The company must ensure that each blind specimen is undistinguishable to the laboratory from a normal specimen.

a. The company must submit blind specimens to the laboratory using the same channels (e.g., via a regular collection site) through which employee specimens are sent to the laboratory.

b. The company 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.

c. The company must ensure that all blind specimens include split specimens.

C. Investigations and False Positive.

1. PHMSA or FMCSA shall investigate, or shall refer to DHHS for investigation, any unsatisfactory performance testing result and, based on this investigation; the laboratory shall take action to correct the cause of the unsatisfactory performance test result. A record shall be made of the investigative findings and the corrective action taken by the laboratory, and that record shall be dated and signed by the individual responsible for the day to day management and operation of the drug testing laboratory. PHMSA or FMCSA shall send the document to the company as a report of the unsatisfactory performance testing incident. PHMSA or FMCSA shall ensure notification of the finding to DHHS.

2. Should a false positive error occur on a blind performance test specimen and the error is determined to be an administrative error (clerical, sample mix-up, etc.), the company shall promptly notify PHMSA or FMCSA. PHMSA or FMCSA and the company shall require the laboratory to take corrective action to minimize the occurrence of the particular error in the future, and, if there is reason to believe the error could have been systemic, PHMSA or FMCSA may also require review and reanalysis of previously run specimens.

3. Should a false positive error occur on a blind performance test specimen and the error is determined to be a technical or methodological error, the company shall instruct the laboratory to submit all quality control data from the batch of specimens which included the false positive specimen to PHMSA or FMCSA. In addition, the laboratory shall retest all specimens analyzed positive for that drug or metabolite from the time of final resolution of the error back to the time of the last satisfactory performance test cycle. This retesting shall be documented by a statement signed by the individual responsible for day-to-day management of the laboratory's urine drug testing. PHMSA or FMCSA may require an on-site review of the laboratory that may be conducted unannounced during any hours of operation of the laboratory. DHHS has the option of revoking or suspending the laboratory's certification or recommending that no further action be taken if the case is one of less serious error in which corrective action has already been taken, thus reasonably assuring that the error will not occur again.

IX. MEDICAL REVIEW OFFICERS AND THE VERIFICATION PROCESS (49 CFR PART 40 SUBPART G)

A. Medical Review Officer Qualifications.

1. Qualification of Medical Review Officer (§40.121) - To be qualified to act as an MRO in the DOT drug testing program, the MRO must meet each of the requirements of this section:

   a. Credentials. The MRO must be a licensed physician (Doctor of Medicine or Osteopathy). If the MRO is 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 the MRO is licensed as an M. D. in one state or province in the U. S., Canada, or Mexico, the MRO is not limited to performing MRO functions in that state or province, and may perform MRO functions for employees in other states or provinces without becoming licensed to practice medicine in the other jurisdictions.

   b. Basic knowledge. The MRO must be knowledgeable in the following areas:

      (1) The MRO 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) The MRO 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) The MRO must be knowledgeable about this part, the DOT MRO Guidelines, and the DOT agency regulations applicable to the employers for whom the MRO evaluates drug test results, and you must keep current on any changes to these materials. The DOT MRO Guidelines document is available from ODAPC.

   c. Qualification training. The MRO must receive qualification training meeting the requirements of this paragraph.

      (1) Qualification training must provide instruction on the following subjects:

         (a) Collection procedures for urine specimens;

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

         (c) Interpretation of drug and validity tests results;

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

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

         (f) Provisions of 49 CFR Part 40 and DOT agency rules applying to employers for whom the MRO reviews test results, including changes and updates to 49 CFR Part 40 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 the completion of qualification training under paragraph 1.c.1. of this section, the MRO 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 1.c.1. of this section.

(3) The following is the schedule for qualification training you must meet:

(a) If the MRO became an MRO before August 1, 2001, and have already met the qualifications training requirement, the MRO does not have to meet it again.

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

(c) If the MRO became an MRO on or after August 1, 2001, the MRO must meet the qualifications training requirement before to performing MRO functions.

d. Continuing Education. During each three-year period from the date on which the MRO satisfactorily completed the examination under paragraph 1.c.2. of this section, the MRO 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 the MRO met the qualification training requirements of this section.

(2) The MRO continuing education activities must include assessment tools to assist you in determining whether you have adequately learned the material.

(3) The MRO who has completed the qualification training and examination requirements prior to August 1, 2001 must complete his/her first increment of 12 CEU hours before August 1, 2004.

e. Documentation. The MRO must maintain documentation showing that he/she currently meet all requirements of this section. The MRO must provide this documentation on request to DOT agency representatives and to employers and C/TPA's who are using or negotiating to use the MRO services.

B. Medical Review Officer Responsibilities in the DOT Drug Testing Program (§40.123).

1. The MRO must 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). The MRO, is 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 company's, 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. The company or service agent is 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. The MRO must determine whether there is a legitimate medical explanation for confirmed positive, adulterated, substituted, and invalid drug tests results from the laboratory.

d. While the MRO provides 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. The MRO 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. The MRO must ensure the timely flow of test results and other information to employers.

g. The MRO must protect the confidentiality of the drug testing information.

h. The MRO must perform all your functions in compliance with this part and other DOT agency regulations.

C. Criteria for MRO and Laboratory Relationship (§40.125).

The MRO 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. The MRO 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).

D. Medical Review Officer Functions in Reviewing Negative Test Results (§40.127).

1. The MRO must do the following with respect to negative drug test results received 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 reporting a negative test result, the MRO must have in their 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, or 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 the MRO by the collector or laboratory appears unclear, the MRO 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 the MRO's 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 the MRO's direction, personal supervision may the administrative functions of this section for the MRO, but only the MRO can cancel a test. If the MRO cancels a laboratory-confirmed negative result, check the "Test Cancelled" box (Step 6) on Copy 2 of the CCF, make the appropriate annotation in the "Remarks" line, provide his/her name, and sign, initial or stamp and date the verification statement.

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

      (2) The MRO is 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, the MRO need not review more than 500 negative results in any quarter.

(3) The MRO review must, as a minimum, include the CCF, negative laboratory test result, any accompanying corrective documents, and the report sent to the company. The MRO must correct any errors that he/she discovers. The MRO must take action as necessary to ensure compliance by the MRO's staff with 49 CFR Part 40 and document the corrective action. The MRO must attest to the quality assurance review by initialing the CCFs that you review.

(4) The MRO must make these CCFs easily identifiable and retrievable by the MRO for review by DOT agencies.

E. Medical Review Officer Functions in Reviewing Laboratory - Confirmed Positive, Adulterated, Substituted, or Invalid Drug Test Results (§40.129).

1. The MRO must do the following with respect to confirmed positive, adulterated, substituted, or invalid drug tests received from a laboratory, before 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 the MRO to cancel the test (see §40.199 and 40.203). Staff under the MRO's direct personal supervision may conduct this administrative review, but only the MRO may verify or cancel a test.

   b. 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. The MRO is 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).

   c. If the copy of the documentation provided to the MRO by the collector or laboratory appears unclear, the MRO must request that the collector or laboratory send a legible copy.

   d. 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 the MRO and the employee. The MRO may initiate the verification process based on the laboratory results report.

   e. 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.

2. Before the MRO can report a verified negative, positive, test cancelled, refusal to test because of adulteration or substitution, the MRO must have in his/her possession the following documents:

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

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

3. 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.

4. If the MRO cancels a laboratory confirmed positive, adulterated, substituted, or invalid drug test report, check the "test cancelled" box (Step 6) on Copy 2 of the CCF, make appropriate annotation in the "Remarks" line, sign, provide his/her name, and date the verification statement.

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

6. 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.

7. The MROs action concerning reporting confirmed positive, adulterated, or substituted results to the employer before he/she has completed the verification process are also governed by the stand-down provisions of §40.21.

   a. If a company has a stand-down policy that meets the requirements of §40.21, the MRO may report to the

DER an employee's laboratory confirmed positive, adulterated, or substituted test result, consistent with the terms of the waiver the company received. The MRO must not provide any further details about the test result (e. g., the name of the drug involved).

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

F. MRO or DER Notification to an employee of the Verification Process - After a Confirmed Positive, Adulterated, Substituted, or Invalid Test Result (§40.131).

1. When the MRO receives a confirmed positive, adulterated, substituted, or invalid test result from the laboratory, the MRO 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, the MRO must explain to the employee that, if he or she declines to discuss the result, the MRO will verify the test as positive or as a refusal to test because of adulteration or substitution, as applicable.

2. The MRO staff under his/her personal supervision may conduct this initial contact for the MRO.

   a. This staff contact must be limited to scheduling the discussion between the MRO and the employee and explaining the consequences of the employee's declining to speak with the MRO (i.e., that the MRO will verify the test without input from the employee). If the employee declines to speak to the MRO, the staff person must document the employee's decision, including the date and time.

   b. A staff person must not gather any medical information or information concerning possible explanations for the test result.

   c. 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.

   d. Since the MRO is required to speak personally with the employee, face-to-face or on the phone, the MRO's staff must not inquire if the employee wishes to speak to the MRO.

3. The MRO or his/her 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 the MRO or his/her staff cannot reach the employee directly after making these efforts, the MRO or his/her staff must take the following steps:

   a. Document the efforts the MRO or staff made to contact the employee, including dates and times. If both phone numbers are incorrect (e. g., disconnected, wrong number), the MRO or staff may take the actions listed in paragraph (c)(2) of this section without waiting the full 24-hour period.

   b. Contact the DER, instructing the DER to contact the employee.

      (1) The MRO simply direct the DER to inform the employee to contact you.

      (2) The MRO must not inform the DER that the employee has a confirmed positive, adulterated, substituted, or invalid test result.

      (3) The MRO must document the dates and times of attempts to contact the DER, and the MRO must document the name of the DER contacted and the date and time of the contact.

4. The DER 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 the DER successfully contacts the employee (i.e., actually talk to the employee), the DER must document the date and time of the contact, and inform the MRO. The DER should inform the employee that he or she must contact the MRO

immediately. The DER must also inform the employee of the consequences of failing to contact the MRO within the next 72 hours (see § 40.133(a)(2)).

a. The DER must not inform anyone else working for the company that the MRO is seeking to contact the employee on behalf of the MRO.

b. The DER shall have made all reasonable efforts to contact the employee but failed to do so the DER 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.

(1) The DER must document the dates and times of these efforts.

(2) If the DER is unable to contact the employee within this 24-hour period, the DER 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.

G. Circumstances Where MRO May Verify a Test as Positive, or as a Refusal to Test - Because of Adulteration or Substitution, Without Interviewing The Employee (§40.133).

1. The MRO 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 the MRO may verify such a result without an interview:

a. The MRO 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 the MRO. The MRO 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 MRO.

b. DER has successfully made and documented a contact with the employee and instructed the employee to contact the MRO and more than 72 hours have passed since the time the DER contacted the employee.

c. The MRO may verify a test result as a positive or refusal to test, as applicable, if neither the MRO 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.

2. The MRO when verifying a test result as a positive or refusal to test under this section, the MRO must document the date, time and reason, following the instructions in §40.163.

3. The MRO, after having verified a test result as a positive or refusal to test under this section and reported the result to the DER, the MRO must allow the employee to present information to the MRO 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, the MRO may reopen the verification, allowing the employee to present information concerning whether there is a legitimate medical explanation for the confirmed test result.

H. MRO Criteria for Employee Notification in Verification Process - What the MRO tells the employee at the beginning of the verification interview (§40.135).

1. The MRO must tell the employee that the laboratory has determined that the employee's test result was positive, adulterated, substituted, or invalid, as applicable. The MRO 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.

2. The MRO must explain the verification interview process to the employee and inform the employee that the MRO decision will be based on information the employee provides in the interview.

3. The MRO must explain that, if further medical evaluation is needed for the verification process, the employee must comply with the MRO's request for this evaluation and that failure to do so is equivalent of expressly declining to discuss the test result.

4. The MRO must warn an employee who has a confirmed positive, adulterated, substituted or invalid test that the MRO 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).

    a. The MRO must give this warning to the employee before obtaining any medical information as part of the verification process.

    b. For purposes of paragraph 4 of this section, 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.

    c. For purposes of paragraph 4 of this section, 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.

5. The MRO must also advise the employee that, after informing any third party about any medication the employee is using pursuant to a legally valid prescription under the Controlled Substances Act, the MRO will allow 5 days for the employee to have the prescribing physician contact the MRO to determine if the medication can be changed to one that does not make the employee medically unqualified or does not pose a significant safety risk. If, the MRO receives such information from the prescribing physician, the MRO must transmit this information to any third party to whom the MRO previously provided information about the safety risks of the employee's other medication.

I. Basis for the MRO to verify test results - Involving marijuana, cocaine, amphetamines, or PCP (§40.137).

1. The MRO 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.

2. The MRO must offer the employee an opportunity to present a legitimate medical explanation in all cases.

3. 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. The MRO has discretion to extend the time available to the employee for this purpose for up to five days before verifying the test result, if the MRO determines 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.

4. If the MRO determines that there is a legitimate medical explanation the MRO must verify the test result as negative. Otherwise, the MRO must verify the test result as positive.

5. In determining whether a legitimate medical explanation exists, the MRO may consider the employee's use of a medication from a foreign country. The MRO must exercise professional judgment consistently with the following principles:

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

    b. 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.

    c. 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.

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

J. Basis for The MRO to Verify Test Results Involving Opiates (§40.139).

1. The MRO must proceed as follows when receiving a laboratory confirmed positive opiate result:

   a. If the laboratory detects the presence of 6-acetylmorphine (6-AM) in the specimen the MRO 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, the MRO 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, the MRO must verify a confirmed positive test result for opiates only if the MRO determines 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) The MRO is responsible to use his/her best professional and ethical judgment and discretion to determine whether there is clinical evidence of unauthorized use of opiates. Examples of information that you may consider in making this judgment include, but are not limited to, the following:

         (a) Recent needle tracks;

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

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

         (d) 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)(a) and (ii) of this section, personal observation of the employee is essential.

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

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

      (3) To be the basis of a verified positive result for opiates, the clinical evidence the MRO finds 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, the MRO doesn't have grounds for verifying the test positive. The admission must be for the substance that was found).

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

K. Procedure for the MRO to Obtain Information for The Verification Decision (§40.141).

1. The MRO must do the following in making the determinations needed for a verification decision:

a. The MRO must conduct a medical interview. The MRO must review the employee's medical history and any other relevant biomedical factors presented to you by the employee. The MRO 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, the MRO must review and take all reasonable and necessary steps to verify the authenticity of all medical records the employee provides. The MRO may contact the employee's physician or other relevant medical personnel for further information.

L. Criteria for MRO to Verify Test Results Involving Adulteration or Substitution (§40.145).

1. The MRO, upon receipt from the laboratory that a laboratory report indicates a specimen is adulterated or substituted, the MRO must treat that report in the same way the MRO would treat the laboratory's report of a confirmed positive test for a drug or drug metabolite.

2. The MRO 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.

3. In the verification interview, the MRO must explain the laboratory findings to the employee and address technical questions or issues the employee may raise.

4. The MRO 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.

5. The employee has the burden of proof that there is a legitimate medical explanation.

   a. 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.

   b. 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 the creatinine and specific gravity criteria of §40.93(b).

   c. The employee must present information meeting this burden at the time of the verification interview. The MRO has discretion to extend the time available to the employee for this purpose for up to five days before verifying the specimen, if the MRO determines 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.

6. The MRO and/or the company is not responsible for arranging, conducting, or paying for any studies, examinations or analyses to determine whether a legitimate medical explanation exists.

7. The MRO must exercise his/her best professional judgment in deciding whether the employee has established a legitimate medical explanation.

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

   b. If the MRO believes that the employee's explanation may present a reasonable basis for concluding that there is a legitimate medical explanation, the MRO must direct the employee to obtain, within the five-day period set forth in paragraph 5.(c) of this section, a further medical evaluation. This evaluation must be performed by a licensed physician (the " referral physician"), acceptable to the MRO with expertise in the medical issues raised by the employee's explanation. (The MRO may perform this evaluation if the MRO has appropriate expertise.)

      (1) The MRO and/or company is not responsible for finding or paying a referral physician. However, on request of the employee, the MRO or company 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 the MRO or company.

(2) The MRO 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, the MRO 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 7.c. through 7.d. of this section; and

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

c. As the referral physician, the MRO must evaluate the employee and consider any evidence the employee presents concerning the employee's medical explanation. The MRO 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.

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

e. If the MRO determines that there is a legitimate medical explanation, the MRO 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).

f. If the MRO determines that there is not a legitimate medical explanation, the MRO must report the test to the DER as a verified refusal to test because of adulteration or substitution.

g. 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).

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

(b) 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 7 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).

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

(b) 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).

M. MRO Procedures to Change Verified Positive Drug Test Result or Refusal to Test (§40.149).

1. The MRO may change a verified positive or refusal to test drug test result only in the following situations:

   a. When the MRO has reopened a verification that was done without an interview with an employee (see §40.133(c)).

   b. If the MRO receives information, not available to him/her 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. The MRO verified the test results as reported. Then the laboratory notifies the MRO that it mixed up the two test results, and X was really negative and Y was really positive. The MRO would change X's test result from positive to negative and contact Y to conduct a verification interview.

   c. If, within 60 days of the original verification decision-

      (1) The MRO receives information that could not reasonably have been provided to the MRO 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

      (2) The MRO receives credible new or additional evidence that a legitimate medical explanation for an adulterated or substituted result exists. Example to Paragraph 1.c: If the employee's physician provides you a valid prescription that he or she failed to find at the time of the original verification, the MRO may change the test result from positive to negative if the MRO concludes that the prescription provides a legitimate medical explanation for the drug(s)/ metabolite(s) in the employee's specimen.

   d. If the MRO receives the information in paragraph 1.c. of this section after the 60-day period, you must consult with ODAPC prior to changing the result.

   e. When the MRO has made an administrative error and reported an incorrect result.

2. If the MRO changes the result, the MRO must immediately notify the DER in writing, as provided in §40.163-40.165.

3. The MRO is the only person permitted to change a verified test result, such as a verified positive test result or a determination that an individual has refused to test because of adulteration or substitution. This is because the MRO has the sole authority under this part to make medical determinations leading to a verified test (e.g., a determination that there was or was not a legitimate medical explanation for a laboratory test result). For example, an arbitrator is not permitted to overturn the medical judgment of the MRO that the employee failed to present a legitimate medical explanation for a positive, adulterated, or substituted test result of his or her specimen.

N. MRO Prohibitions Concerning the Verification Process - What are MROs Prohibited from Doing as Part of The Verification Process (§40.151) - The MRO is prohibited from doing the following as part of the verification process:

1. The MRO 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 the MRO he/she went to his/her 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/her DOT specimen, the MRO is required to ignore this test result.

2. It is not the MRO's function to make decisions about factual disputes between the employee and the collector concerning matters occurring at the collection site that are not reflected on the CCF (e.g., concerning allegations that the collector left the area or left open urine containers where other people could access them).
3. It is not the function of the MRO to determine whether the company should have directed that a test occur. For example, if an employee tells you that the company misidentified him/her as the subject of a random test, or directed him/her to take a reasonable suspicion or post-accident test without proper grounds under a DOT agency drug or alcohol regulation, the MRO must inform the employee that you cannot play a role in deciding these issues.

4. It is not the function of the MRO 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 the MRO that someone slipped amphetamines into his/her drink at a party, that he/she unknowingly ingested a marijuana brownie, or that he/she traveled in a closed car with several persons 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, the MRO must not declare a test as negative based on an explanation of this kind.

5. The MRO 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).

6. The MRO 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. The MRO 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.

7. The MRO 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.

8. The MRO 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.

9. The MRO 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.

O. MRO Notification to Employees on Their Right to a Test of the Split Specimen (§40.153).

1. The MRO, when verifying a drug test as positive for a drug or drug metabolite, or as a refusal to test because of adulteration or substitution, must notify the employee of his or her right to have the split specimen tested. The MRO must also notify the employee of the procedures for requesting a test of the split specimen.

2. The MRO must inform the employee that he or she has 72 hours from the time the MRO provides this notification to him or her to request a test of the split specimen.

3. The MRO must tell the employee how to contact the MRO to make this request. The MRO must provide telephone numbers or other information that will allow the employee to make this request. The MRO 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 the MRO office to answer the phone).

4. The MRO must tell the employee that if he or she makes this request within 72 hours, the company 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. The MRO must also tell the employee that the company may seek reimbursement for the cost of the test (see §40.173).

5. The MRO must tell the employee that additional tests of the specimen (e.g., DNA tests) are not authorized.

P. MRO Procedures When A Negative or Positive Test Result is also Dilute (§40.155).

1. When the laboratory reports that a specimen is dilute, the MRO must report to the DER that the specimen, in addition to being negative or positive, is dilute.

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

3. The MRO may only report a dilute test result when the MRO is in possession of a legible copy of Copy 1 of the CCF. In addition, the MRO must have Copy 2 of the CCF, a legible copy of it, or any other copy of the CCF containing the employee's signature.

4. When the MRO reports a dilute specimen to the DER, the MRO must explain to the DER the employer's obligations and choices under § 40.197.

Q. MRO Procedures When A Drug Test Result is Invalid (§40.159).

1. The MRO, when the laboratory reports that the test result is an invalid result, the MRO must do the following:

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

   b. 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.

   c. After explaining the limits of disclosure (see §40.135(d) and 40.327), the MRO should inquire as to medications the employee may have taken that may interfere with some immunoassay tests.

   d. If the employee gives an explanation that is acceptable, the MRO must:

      (1) 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.

      (2) 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).

   e. 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:

      (1) 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.

      (2) 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.

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

2. The MRO may only report an invalid test result when the MRO is in possession of a legible copy of Copy 1 of the CCF. In addition, the MRO must have Copy 2 of the CCF, a legible copy of it, or any other copy of the CCF containing the employee's signature.

3. If the employee admits to having adulterated or substituted the specimen, the MRO must, on the same day, write and sign a statement of what the employee said. The MRO must then report a refusal to test in accordance with § 40.163.

R. MRO Procedures When A Drug Test Specimen is Rejected for Testing (§40.161) - The MRO shall when notified by the laboratory the specimen is rejected for testing (e. g., because of a fatal or uncorrected flaw), the MRO must do the following:

1. 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.

2. 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).

3. The MRO may only report a test cancelled because of a rejected for testing test result when the MRO is in possession of a legible copy of Copy 1 of the CCF. In addition, the MRO must have Copy 2 of the CCF, a legible copy of it, or any other copy of the CCF containing the employee's signature.

S. MRO Reporting of Test Results (§40.163).

1. The MRO has a responsibility to report all drug test results to the company.

2. The MRO may use a signed or stamped and dated legible photocopy of Copy 2 of the CCF to report test results.

3. If the MRO does not report test results using Copy 2 of the CCF for this purpose, the MRO must provide a written report (e.g., a letter) for each test result. This report must, as a minimum, include the following information:

   a. Full name, as indicated on the CCF, of the employee tested;

   b. Specimen ID number from the CCF and the donor SSN or employee ID number;

   c. Reason for the test, if indicated on the CCF (e.g., random, post-accident);

   d. Date of the collection;

   e. Date you received Copy 2 of the CCF;

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

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

   h. For cancelled tests, the reason for cancellation; and

   i. For refusal to test, the reason for the refusal determination (e.g., in the case of an adulterated test result, the name of the adulterant).

4. As an exception to the reporting requirements of paragraph S.2. and S.3. of this section, the MRO may report negative results using an electronic data file.

   a. If the MRO reports negatives using an electronic data file, the report must contain, as a minimum, the information specified in paragraph S.3. of this section, as applicable for negative test results.

   b. In addition, the report must contain the MRO's name, address, and phone number, the name of any person other than the MRO reporting the results, and the date the electronic results report is released.

5. The MRO must retain a signed or stamped and dated copy of Copy 2 of the CCF in your records. If the MRO does not use Copy 2 for reporting results, the MRO must maintain a copy of the signed or stamped and dated letter in addition to the signed or stamped and dated Copy 2. If the MRO uses the electronic data file to report negatives, the MRO must maintain a retrievable copy of that report in a format suitable for inspection and auditing by a DOT representative.

6. The MRO must not use Copy 1 of the CCF to report drug test results.

7. The MRO must not provide quantitative values to the DER or C/TPA for drug or validity test results. However, the MRO must provide the test information in his/her possession to a SAP who consults with you (see Sec. 40.293(g)).

T. Procedures for MRO's to Transmit Drug Test Results (§40.165).

1. The MRO must report all drug test results to the DER, except in the circumstances provided for in §40.345.

2. If the company elects to receive reports of results through a C/TPA, acting as an intermediary as provided in §40.345, the MRO must report the results through the designated C/TPA.

U. Procedures for MRO Reporting of Drug Results to The Company (§40.167) -

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

1. The MRO must report the results in a confidential manner.

2. The MRO 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.

   a. Direct telephone contact with the DER is the preferred method of immediate reporting. Follow up the phone call with appropriate documentation (see §40.163).

   b. The MRO is responsible for identifying himself/herself to the DER, and the DER must have a means to confirm the MRO's identification.

   c. The MRO's report that is transmitted to the company must contain all of the information required by §40.163.

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

   a. The MRO must fax, courier, mail, or electronically transmit a legible image or copy of either the signed or stamped and dated Copy 2 or the written report (see Sec. 40.163(b) and (c)).

   b. Negative results reported electronically (i.e., computer data file) do not require an image of Copy 2 or the written report.

4. 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.

5. MRO reports are not subject to modification or change by anyone other than the MRO, as provided in§40.149(c)

V. Additional Information Concerning The Role of MROs and The Verification Process - 49 CFR Part 40 (§40.169).

The company 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 canceling 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.

X. PROBLEMS IN DRUG TESTS (49 CFR PART 40 SUBPART I)

A. Procedures regarding a refusal to take a DOT drug test and the consequences (§40.191).

1. An employee has refused to take a drug test if the employee:

   a. Fails to appear for any test (except a pre-employment test) within a reasonable time, as determined by the employer, after being directed to do so by the employer, consistent with applicable DOT agency regulations, after being directed to do so by the employer. This includes the failure of an employee (including an owner-operator) to appear for a test when called by C/TPA (see §40.61(a));

   b. Fails to remain at the testing site until the testing process is complete; provided, that an employee who leaves the testing site before the testing process commences (see §40.63(c)) for a pre-employment test is not deemed to have refused to test.

   c. Fails to provide a urine specimen for any drug test required by this part or DOT agency regulations; provided, that an employee who does not provide a urine specimen because he or she has left the testing site before the testing process commences (see §40.63(c)) for a pre-employment test is not deemed to have refused to test;

   d. 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));

   e. Fails 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));

   f. Fails or decline to take a second test the employer or collector has directed you to take;

   g. Fails to undergo a medical examination or evaluation, as directed by the MRO as part of the verification process, or as directed by the DER under §40.193(d). In the case of a pre-employment drug test, the employee is deemed to have refused to test on this basis only if the pre-employment test is conducted following a contingent offer of employment: or

   h. Fails 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).

2. If the MRO reports that the employee has a verified adulterated or substituted test result, the employee is considered to have refused to take a drug test.

3. An employee who refuses to take a drug test will incur the consequences specified under DOT agency regulations for a violation of those DOT agency regulations.

4. When an employee refuses to participate in the part of the testing process in which the collector is involved, the collector must terminate the portion of the testing process in which the collector is involved, document the refusal on the CCF (including, in the case of the collector, printing the employee's name on Copy 2 of the CCF), immediately notify the DER by any means (e.g., telephone or secure fax machine) that ensures that the refusal notification is immediately received. As a referral physician (e.g., physician evaluating a "shy bladder" condition or a claim of a legitimate medical explanation in a validity testing situation), you must notify the MRO, who in turn will notify the DER.

   a. The collector must note the refusal in the " Remarks" line (Step 2), and sign and date the CCF.

   b. The MRO 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. The MRO must then sign and date the CCF.

5. An employee who refuses to take a non-DOT test or to sign a non-DOT form has not refused to take a DOT test. There are no consequences under DOT agency regulations for refusing to take a non-DOT test.

B. Procedures for an employee who does not provide a sufficient amount of urine for a drug test (§40.193).

1. 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).

2. The collector must do the following:

   a. 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)).

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

   c. If the employee refuses to make the attempt to provide a new urine specimen or leaves the collection site before the collection process is complete, you must discontinue the collection, note the fact on the " Remarks" line of the CCF (Step 2), and immediately notify the DER. This is a refusal to test.

   d. 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.

   e. 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.

3. The DER, when the collector informs him/her that the employee has not provided a sufficient amount of urine (see paragraph 2(d) of this section), the DER 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.)

   a. The MRO, if another physician will perform the evaluation, must provide the other physician with the following information and instructions:

      (1) 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;

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

(3) That the referral physician must agree to follow the requirements of paragraphs 4 through 7 of this section.

4. The referral physician conducting this evaluation must recommend that the MRO make 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 urine. If the MRO accepts this recommendation, the MRO must:

      (1) Check '' Test Cancelled'' (Step 6) on the CCF; and

      (2) Sign and date the CCF.

   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 urine. If the MRO accepts this recommendation, the MRO must:

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

      (2) Sign and date the CCF.

5. 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.

6. The referral physician making the evaluation and, after completing the evaluation, must provide a written statement of his/her recommendations and the basis for them to the MRO. The physician must not include in this statement detailed information on the employee's medical condition beyond what is necessary to explain the conclusion.

7. The referral physician making this evaluation in the case of a pre-employment test, must 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, the physician must set forth his/her determination and the reasons for it in an written statement to the MRO. The MRO, upon receiving such a report must follow the requirements of §40.195, where applicable.

8. The MRO must seriously consider and assess the referral physician's recommendations in making his/her 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. The MRO must report his/her determination to the DER in writing as soon as the determination is made.

9. The company who receives a report from the MRO indicating that a test is cancelled as provided in paragraph (d)(1) of this section, the company can take no further action with respect to the employee. The employee remains in the random testing pool.

C. Criteria for Insufficient Urine on Pre-Employment or Return-to-Duty – Medical Condition - Procedure for an individual who 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 (§40.195).

1. 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. The MRO in this situation must do the following:

   a. The MRO must determine if there is clinical evidence that the individual is an illicit drug user. The MRO 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).

b. If the MRO does not personally conduct the medical evaluation the MRO must ensure that an evaluation conducted by a licensed physician acceptable to the MRO.

c. 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.

2. If the medical evaluation reveals no clinical evidence of drug use the MRO 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.

a. Check " Negative" (Step 6) on the CCF.

b. Sign and date the CCF.

3. If the medical evaluation reveals clinical evidence of drug use the MRO 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).

4. 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.

a. 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.

b. 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.

D. Procedures for the Company Upon Receiving a Report of a Dilute Specimen (§40.197).

1. If the MRO informs the company that a positive drug test was dilute, the company must simply treat the test as a verified positive test. The company must not direct the employee to take another test based on the fact that the specimen was dilute.

2. If the MRO informs the company that a negative drug test was dilute, the company may, but is not required to, direct the employee to take another test immediately. 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)).

3. The company must treat all employees the same for this purpose. For example, the company must not retest some employees and not others. The company may, however, establish different policies for different types of tests (e. g., conduct retests in pre-employment test situations, but not in random test situations). The company must inform employees in advance of the decision on these matters.

4. If the company directs the employee to take another test, the company will ensure that the employee is given the minimum possible advance notice that he or she must go to the collection site.

5. If the company directs the employee to take another test, the result of the second test-not that of the original test-becomes the test of record, on which the company must rely for purposes of this 49 CFR Part 40.

6. If the company requires employees to take another test, and the second test is also negative and dilute, the company is not permitted to make the employee take a third test because the second test was dilute.

7. If the company directs the employee to take another test and the employee declines to do so, the employee has refused the test for purpose of this part and DOT agency regulations.

E. Problems that cause a drug test to be cancelled (§40.199).

1. When the laboratory discovers a "fatal flaw" during its processing of incoming specimens (see § 40.83), the laboratory will report to the MRO that the specimen has been "Rejected for Testing" (with the reason stated). The MRO must always cancel such a test.

2. The following are "fatal flaws":

   a. There is no printed collector's name and no collector's signature;

   b. The specimen ID numbers on the specimen bottle and the CCF do not match;

   c. The specimen bottle seal is broken or shows evidence of tampering (and a split specimen cannot be redesignated, see §40.83(g)); and

   d. 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)).

3. The MRO must report the result as provided in §40.161.

F. Problems that cause a drug test to be cancelled and may result in a requirement for another collection (§40.201) - The MRO must cancel a drug test when a laboratory reports that any of the following problems have occurred. The MRO must inform the DER that the test was cancelled. The MRO 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.

1. The laboratory reports a "Invalid Result. " The MRO must follow applicable procedures in §40.159 (recollection under direct observation may be required).

2. The laboratory reports the result as "Rejected for Testing." The MRO must follow applicable procedures in §40.161 (a recollection may be required).

3. 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." The MRO must follow applicable procedures in § 40.187(b) (no recollection is required in this case).

4. 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. The MRO must follow applicable procedures in § 40.187(c) (no recollection is required in this case).

5. The laboratory's test of the primary specimen is positive, adulterated, or substituted and the split specimen is unavailable for testing. The MRO must follow applicable procedures in §40.187(d) (recollection under direct observation is required in this case).

6. The examining physician has determined that there is an acceptable medical explanation of the employee's failure to provide a sufficient amount of urine. The MRO must follow applicable procedures in §40.193(d)(1) (no recollection is required in this case).

G. Problems that cause a drug test to be cancelled unless they are corrected (§40.203).

1. 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 the MRO that the specimen has been "Rejected for Testing" (with the reason stated).

2. The following is a ‘‘correctable flaws’’ that laboratories must attempt to correct:

   a. The collector’s signature is omitted on the certification statement on the CCF.

   b. The specimen temperature was not checked and the ‘‘Remarks’’ line did not contain an entry regarding the temperature being out of range.

3. When the MRO discovers a "correctable flaw" during the review of the CCF, the MRO must cancel the test unless the flaw is corrected.

4. The following are correctable flaws that the MRO must attempt to correct:

   a. 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.
   b. The certifying scientist's signature is omitted on the laboratory copy of the CCF for a positive, adulterated, substituted, or invalid test result.

   c. The collector uses a non-Federal form or an expired Federal form for the test. This flaw may be corrected through the procedure set forth §40.205(b)(2), provided that the collection testing process has been conducted in accordance with the procedures of this part in an HHS-certified laboratory. During the period August 1 – October 31, 2001, the MRO is not required to cancel a test because of the use of an expired Federal form. Beginning November 1, 2001, if the problem is not corrected, the MRO must cancel the test.

H. Correction of drug test problems (§40.205).

1. The collector has the responsibility of trying to successfully complete a collection procedure for each employee.

   a. If, during or shortly after the collection process, the collector becomes aware of any event that prevents the completion of a valid test or collection (e. g., a procedural or paperwork error), the collector must try to correct the problem promptly, if doing so is practicable. The collector may conduct another collection as part of this effort.

   b. If another collection is necessary, the collector must begin the new collection procedure as soon as possible, using a new CCF and a new collection kit.

2. If the collector, laboratory, MRO, company, or other person implementing these drug testing regulations becomes aware of a problem that can be corrected (see §40.203), but which has not already been corrected under paragraph (a) of this section, they must take all practicable action to correct the problem so that the test is not cancelled.

   a. If the problem resulted from the omission of required information, they 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 the collector and forgot to make a notation on the "Remarks" line of the CCF that the employee did not sign the certification. The collector would, when the problem is called to his/her attention, supply a signed statement that the employee failed or refused to sign the certification and that your statement is true and accurate. The collector must supply this information on the same business day on which you are notified of the problem, transmitting it by fax or courier.

   b. If the problem is the use of a non-Federal form or an expired Federal form, you must provide a signed statement (i.e. a memorandum for the record). It must state that the incorrect form contains all the

information needed for a valid DOT drug test, 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 taken to prevent future use of non-Federal forms or expired Federal forms for DOT tests. For this flaw to be corrected, the test of the specimen must have occurred at a HHS-certified laboratory where it was tested consistent with the requirements of 49 CFR Part 40. The person must supply this information on the same business day on which notified of the problem, transmitting it by fax or courier.

c. The responsible person must maintain the written documentation of a correction with the CCF.

d. The responsible person 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 he/she has corrected the flaw.

3. If the correction does not take place the MRO must cancel the test.

I. Effects of a cancelled drug test (§40.207).

1. A cancelled drug test is neither positive nor negative.

   a. The company 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).

   b. The company 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).

   c. However, the company must not direct a recollection for an employee because a test has been cancelled, except in the situations cited in paragraph (a)(2) of this section or other provisions of this part that require another test to be conducted (e. g., §40.159(a)(5) and 40.187(b)).

2. A cancelled test does not count toward compliance with DOT requirements (e.g., being applied toward the number of tests needed to meet the company's minimum random testing rate).

3. A cancelled DOT test does not provide a valid basis for the company to conduct a non-DOT test (i.e., a test under company authority).

J. Problems that require corrective action but does not result in cancellation of test (§40.208).

1. If, as a laboratory, collector, company, or other person implementing the DOT drug testing program, he/she becomes aware that the specimen temperature on the CCF was not checked and the ``Remarks'' line did not contain an entry regarding the temperature being out of range, he/she must take corrective action, including securing a memorandum for the record explaining the problem and taking appropriate action to ensure that the problem does not recur.

2. This error does not result in the cancellation of the test.

3. When the company or service agent, who caused this error, even though not sufficient to cancel a drug test result, may subject the company or service agent to enforcement action under DOT agency regulations or Subpart R of 49 CFR Part 40.

K. Effects of procedural problems that are not sufficient to cancel a drug test (§40.209).

1. The collector, laboratory, MRO, company or other person administering the drug testing process must document any errors in the testing process of which he/she becomes 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 (2) of this section.

2. 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:

   a. 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);

   b. 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);

   c. 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;

   d. A delay in the collection process (see §40.61(a));
   e. 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));

   f. 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;

   g. The fact that a test was conducted in a facility that does not meet the requirements of § 40.41;

   h. If the specific name of the courier on the CCF is omitted or erroneous;

   i. Personal identifying information is inadvertently contained on the CCF (e. g., the employee signs his or her name on the laboratory copy); or

   j. Claims that the employee was improperly selected for testing.

3. The company, when these types of errors occur, even though not sufficient to cancel a drug test result, may subject the company to enforcement action under DOT agency regulations.

XI. RETENTION OF SAMPLES AND ADDITIONAL TESTING

A. General.

Samples that yield positive results on confirmation must be retained by the laboratory in properly secured, long-term, frozen storage for at least 365 days.

B. Retention Period.

1. Within this 365 day period, the employee or designated representative, PHMSA, FMCSA, or other state agencies with jurisdiction, or the company may request in writing that the sample be retained for an additional period.

2. If the laboratory does not receive the request to retain the sample within the 365 day period, the sample may be discarded.

C. Additional Testing

If the medical review officer determines there is no legitimate medical explanation for a confirmed positive test result other than the unauthorized use of a prohibited drug, and if timely additional testing is requested by the employee according to DOT Procedures, the split specimen must be tested.

XII. EMPLOYEE ASSISTANCE PROGRAM (EAP)

A. Scope of Program.

The EAP will provide education and training on drug use to all employees. The education shall include:

1. Informational material displayed on bulletin boards, employee break rooms, locker rooms, etc., and distributed to employees.

2. A community service hot-line telephone number for employee assistance displayed on bulletin boards and distributed to employees, and

3. Distribution of the company's policy regarding the use of prohibited drugs to all new employees. The policy shall be displayed in prominent places throughout the company (i.e., employee bulletin board, break room, locker rooms).

B. Supervisor Training.

Supervisory personnel responsible for those employees covered under Parts 199 & 382 will receive training under the anti-drug plan. The training shall include at least one 60-minute period of training on the specific, contemporaneous physical, behavioral, and performance indicators of probable drug use. This training shall be for supervisors who may determine whether an employee must be drug tested for reasonable cause.

XIII. CONFIDENTIALITY AND RELEASE OF INFORMATION (PART 40 - SUBPART P)

A. General confidentiality rule for drug and alcohol test information (§40.321) - Except as otherwise provided in 49 CFR Part 40 the service agent or company participating in the DOT drug or alcohol testing process is prohibited from releasing individual test results or medical information about an employee to third parties without the employee's specific written consent.

1. 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.

2. "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.

B. Criteria for program participant's release of drug or alcohol test information in connection with legal proceedings (§40.323).

1. The company may release information pertaining to an employee's drug or alcohol test without the employee's consent in certain legal proceedings.

   a. These proceedings include a lawsuit (e.g., a wrongful discharge action), grievance (e.g., an arbitration concerning disciplinary action taken by the company), 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).

   b. 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 company is authorized to respond to the court's order to produce the records.

2. In such a proceeding the company may release the information to the decision-maker in the proceeding (e. g., the court in a lawsuit). The company may release the information only with a binding stipulation that the decision-maker to whom it is released will make it available only to parties to the proceeding.

3. If a service agent receives a company request for its employee's drug or alcohol testing information from the service agent to use in a legal proceeding as authorized in paragraph B.1. of this section (e.g., the laboratory's data package) the service agent must provide the requested information to the company.

4. The company or service agent must immediately notify the employee in writing of any information they release under this section.

C. MRO procedures regarding release of medical information gathered in verification process (§40.327).

1. The MRO must, except as provided in paragraph (3) 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 the MRO determines in their reasonable medical judgment, that:

   a. The information is likely to result in the employee being determined to be medically unqualified under an applicable DOT agency regulation; or

   b. The information indicates that continued performance by the employee of his or her safety-sensitive function is likely to pose a significant safety risk.

2. 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.

3. If the law of a foreign country (e.g., Canada) prohibits the MRO from providing medical information to the employer, you may comply with that prohibition.

D. Information laboratories, MROs, and other service agents must release to employees (§ 40.329).

1. The MRO or service agent 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. The MRO or service agent may charge no more than the cost of preparation and reproduction for copies of these records.

2. The laboratory 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). The laboratory may charge no more than the cost of preparation and reproduction for copies of these records.

3. The SAP must make available to an employee, on request, a copy of all SAP reports (see § 40.311).

E. Additional parties that companies and service agents must release information (§40.331) - The company or service agent must release information under the following circumstances:

1. If the company or service agent receives a specific written consent from an employee authorizing the release of information about that employee's drug or alcohol tests to an identified person the employer or service agent

must provide the information to the identified person. For example, as a company, when you receive a written request from a former employee to provide information to a subsequent company the company or service agent must do so. In providing the information the company or service agent must comply with the terms of the employee's consent.

2. The company must, upon request of DOT agency representatives must provide the following:

   a. Access to the company facilities used for 49 CFR Part 40 and DOT agency drug and alcohol program functions.

   b. 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.

3. The service agent must, upon request of DOT agency representatives, provide the following:

   a. Access to the service agent's facilities used for 49 CFR Part 40 and all DOT agency drug and alcohol program functions.

   b. 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 49 CFR Part 40 and DOT agency regulations.

4. If requested by the National Transportation Safety Board as part of an accident investigation the service agent must provide information concerning post-accident tests administered after the accident.

5. If requested by a Federal, state or local safety agency with regulatory authority over the company the company or service agent must provide drug and alcohol test records concerning the employee.

6. Except as otherwise provided in 49 CFR Part 40, the laboratory 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 the release of a specimen or part of a specimen contrary to any provision of 49 CFR Part 40 the laboratory 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. The requirement of 49 CFR Part 40 does not require the laboratory to disobey a court order, however.

F. Records that are maintained by the company (§40.333).

1. The company must keep the following records for the following periods of time:

   a. The company must keep the following records for five years:

      (1) Records of employee alcohol test results indicating an alcohol concentration of 0.02 or greater;

      (2) Records of employee verified positive drug test results;

      (3) Documentation of refusals to take required alcohol and/ or drug tests (including substituted or adulterated drug test results);

      (4) SAP reports; and

      (5) All follow-up tests and schedules for follow-up tests.

   b. The company must keep records for three years of information obtained from previous employers under §40.25 concerning drug and alcohol test results of employees.

c. The company must keep records of the inspection, maintenance, and calibration of EBTs, for two years.

d. The company 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.

2. The company does not have to keep records related to a program requirement that does not apply to you (e.g., a maritime company who does not have a DOT-mandated random alcohol testing program need not maintain random alcohol testing records).

3. The company must maintain the records in a location with controlled access.

4. A service agent may maintain these records for the company. However, the service agent must ensure that the service agent can produce these records at the company's 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 the employer must ensure that the service agent can provide them within two business days.
5. A service agent may store records electronically, where permitted by 49 CFR Part 40, the service agent must ensure that the records are easily accessible, legible, and formatted and stored in an organized manner. If electronic records do not meet these criteria, the service agent must convert them to printed documentation in a rapid and readily auditable manner, at the request of DOT agency personnel.

XIV. RECORDKEEPING PROCEDURES

A. General.

1. The DER (or designee) shall maintain a locked file system that will contain drug test results. This file shall be maintained as confidential. Employee files shall be handled on strict "need to know" basis.

2. Drug tests results shall not be included in personnel files. Information regarding an individual's drug testing result or rehabilitation may be released only upon written consent of the individual, except:

   a. Such information must be released regardless of consent to PHMSA or FMCSA or other government agency as a part of an accident investigation;

   b. Such information may be disclosed regardless of consent in a lawsuit, grievance, or other proceeding initiated by or on behalf of the individual and arising from a verified positive drug test.

3. Information regarding an individual's drug testing results or rehabilitation must be released upon the written consent of the individual and as provided by DOT Procedures.

B. Statistical Data.

Statistical data related to drug testing and rehabilitation that is non name-specified and training records may be released to PHMSA or FMCSA or other governmental agency upon request.

C. Record Retention.

The records that must be maintained are:

1. Records that demonstrate the collection process conforms to 49 CFR Part 40 shall be retained for a 3-year period.

2. Employee drug test results that show positive and test type (pre-employment test, random test, post-accident test, or post rehabilitation test), and records that demonstrate rehabilitation (including the MRO's determination). These records shall be retained for a 5-year period and must include the following information:

   a. Job classification and functions of employee.

   b. Prohibited drug(s) used.

c. Disposition of employee (i.e., rehab, suspension, termination, etc.)

3. Employee drug tests that demonstrate negative results shall be retained for a period of 1 year.

4. A record indicating the total number of employees tested and the results of tests separated into categories shall be retained for a 5-year period.

5. Training records confirming that supervisors and employees have been trained as required under § 199.19, and copies of training material used shall be retained for a 3-year period.

6. All records are maintained, under lock and key by the drug program manager or designated representative.

D. Management Information System (MIS) Requirements.

1. Specific pipeline covered employees information will be maintained to include the following elements:

- Number of employees subject to the PHMSA or FMCSA regulations;
- Number of employees subject to testing under the anti-drug rules of more than one DOT agency, identify each agency;
- Number of specimens collected by type of test (pre-employment, random, reasonable cause/suspicion, post-accident);
- Number of positives verified by a MRO by type of test & controlled substance; Number of negatives verified by MRO by type of test;
- Number of employees verified positive by a MRO who were returned to duty as a covered employee during the reporting period;
- Number of employees with test verified positive by a MRO for multiple controlled substances;
- Number of employees who refused to submit to a controlled substances test;
- Number of supervisors who have received training during the reporting period.

XV. CONTRACTOR/SUB-CONTRACTOR MONITORING

A. General. The contractor company will include a clause in the contracts that drug testing, education, and training may be addressed by the contractor/sub-contractor in accordance with Parts 199, 382, and Part 40 for covered functions. The company shall be responsible for ensuring compliance with the provisions of Parts 199, 382, and 40.

B. Contractor/Sub-Contractor Records.

1. Contractor/Sub-Contractors shall retain copies of appropriate drug testing records as required by 49 CFR Parts 199, 382, and Part 40.

2. The records and access to the contractor/sub-contractor's property shall be readily accessible for inspection by the pipeline operator, contractor, PHMSA, and representatives of those state agencies under which jurisdiction the company operates.

C. Contractor/Sub-Contractor Monitoring.

1. Confirmation of contractor/sub-contractor compliance/monitoring - Specific guidance on how to develop an effective contractor compliance and monitoring program are outlined herein.

2. The company can, as an alternative to the above guidance provide coverage for the contractor/sub-contractors employees by including them in the company's drug testing program for the duration of the contract or work project. When contractor employees are covered under the company's anti-drug plan, the contractor shall ensure that their employees comply with all the provisions contained in the company's drug plan, unless some provisions for exempts are authorized.

D. Procedures for Determining Compliance.

1. Qualifying Potential Contractor/Sub-Contractor(s). Qualifications of the potential contractor as it pertains to drug testing policies/procedures is assured by requesting the potential contractor/sub-contractor to submit a copy of its drug plan for review and compliance with PHMSA/FMCSA/DOT regulations. After review of the drug plan is completed, written correspondence to the contractor/sub-contractor will advise it whether or not the drug plan is acceptable or in need of further additions, deletions, revisions or clarifying language. The review of the contractor/sub-contractor plan shall be completed utilizing the criteria established in the PHMSA and FMCSA Anti-Drug Plan Inspection form. Addendum's made to the contractor's plan shall be attached to the previously submitted drug plan. Upon approval of the addendum, a letter of acceptance is then sent to the contractor. The contractor/sub-contractor is now eligible to bid on company contract work that would be covered under Parts 199, 382, and 40.

2. Monitoring Contractor/Sub-Contractor's Compliance. The contractor/sub-contractor may be required to provide information on their employees who will perform covered functions for the operator. This information may include the name and job title of its employees who will perform any work or functions covered by Parts 199 & 382 under that contract. A list of each contractor's/sub-contractor's covered employees may be distributed to appropriate company field management personnel and job sites.

3. Statistical Submission. All contractors will be required to submit drug testing statistical information on a periodical basis that may be based on the duration of the contract. Typically this requirement will be conducted on a monthly or quarterly basis. The company may require a more frequent schedule for submission of data should they determine a need for such statistics.

4. Statistical Record Retention. The company shall maintain a complete file on each contractor/sub-contractor's statistical drug testing data reports. The company shall make available these reports when requested by the PHMSA or FMCSA Administrator, designated representative, or representatives of those state agencies under which jurisdiction the company operates.

5. Access to Records/Property. The company, contractor/sub-contractor will allow access to property and records by the operator, the Administrator, contractor, and if the operator is subject to the jurisdiction of a state agency, a representative of the state agency for the purpose of monitoring the operator's compliance with the requirements of the regulations.

APPENDIX A

DRUG PROGRAM MANAGER (DPM) or DESIGNATED EMPLOYEREPRESENTATIVE (DER)

City of Mesa's Designated Employer Representative (DER)
Jackie Hale, Personnel Office
Sr. Human Resources Specialist
(480) 644-4414 Office Phone
(480) 381-0086 Cell Phone

Backup to DER
Holly Nelson, Personnel Office
Human Resources Specialist II
(480) 644-3393 Office Phone

City of Mesa's Personnel Office

Mesa City Plaza Building
20 E. Main Street, Suite 130
Mesa, AZ 85210

Mailing Address

City of Mesa Personnel Office
PO Box 1466
Mesa, AZ 85211-1466

MEDICAL REVIEW OFFICER (MRO)

Primary MRO:

Name: **Andrew Yorgason**
Banner Occupational Health Services
MRO Office
1300 N. 12th St., Ste. 405
Phoenix, AZ 85006

Telephone: (602) 747-4890
Fax: (602) 747-3458

Name: **Gerry Hooper, M.D.**
Banner Occupational Health Services
Desert Clinic
2225 W. Southern Avenue
Mesa, AZ 85202

Telephone: (480) 412-3275
Fax: (480) 412-8701
Pager: (602) 223-1722

Secondary MRO:

Name: **Dungchi Nguyen, D.O.**
Banner Occupational Health Services
Gateway Clinic
2940 E. Banner Gateway Drive, Suite 375
Mesa, AZ 85234

Telephone: (480) 543-3300 (Mesa office)
Fax: (480) 543-2694
Pager: (602) 817-7521

Alternate MROs: Robert Buttemiller, M.D. / Dennis Frazier, M.D. / Arlen Rollins, D.O. / V. Jon Williams, M.D. / Dr. Deborah Summers / Dr. Steven Ross / Dr. Susan Maline / Dr. Lisa Fuller

SUBSTANCE ABUSE MENTAL HEALTH LABORATORY (SAMHSA)

Name: Southwest Labortories, Inc.
4645 E. Cotton Center Blvd., Suite 177
Phoenix, AZ 85040

Telephone: (602) 438-8507
Toll Free: (800) 279-0027
Fax: (602) 438-4739

Contact Person: Gary Carmack, PhD., Laboratory Director
Sonja Hoppe, Vice President

COLLECTION SITE(S)

Collection Site #1: Banner Occupational Health Services
Gateway Clinic
1920 N. Higley Road, Suite 108
Gilbert, AZ 85234

Telephone: (480) 543-3300

Hours: Monday – Friday 7:00 a.m. – 6:00 p.m.

Contact Person: Amy Lake, Case Coordinator

(Southwest corner of Higley and Highway 60)

Collection Site #2: City of Mesa Utilities Building
640 N. Mesa Drive
Mesa, AZ 85201

Telephone: Questions related to this procedure should be answered by the DER and the alternates listed above.

(This location is for the on-site collections provided by Banner or MDT Services for random drug and alcohol testing. The collections are performed in the Community meeting rooms just south of the main entrance to the building on a specific day that is selected at a specific time.)

Collection Site #3: MDT Services
PO Box 2123
Sun City, AZ 85372

Telephone: (602) 667-4555

Contact Person: Marty Catalanotte, Owner

SUBSTANCE ABUSE PROFESSIONAL (SAP)

Provider: **ComPsych Corporation**
Worldwide Headquarters
NBC Tower
455 N. Cityfront Plaza Drive
Chicago, IL 60611-5322 Phone (312) 595-4000
www.compsych.com

Telephone: (312) 595-4000

EMPLOYEE ASSISTANCE PROGRAM (EAP)

The Employee Assistant Program offers employees and their family members counseling and referral services at no charge. This program applies to mental health and counseling services only.

Provider: ComPsych Guidance Resources

Telephone: (866) 519-7415

Website: www.guidanceresources.com

Web ID: MESA

APPENDIX B
EMPLOYEES/SUPERVISORY POSTIIONS SUBJECT TO DRUG TESTING

Position Title	Job Code	Applicable DOT Program (click here for Legend)
Aquatics Maintenance Foreman*	4706	FMCSA (2)
Aquatics Maintenance Assistant – Full-time Assignment	3797	FMCSA (2)
Aquatics Maintenance Leader*	4120	FMCSA (2)
Aquatics Maintenance Worker I/II	4026/4107	FMCSA (2)
Construction Equipment/Supply Specialist	4002	PHMSA (3)/FMCSA
Container Repair Worker	3834	FMCSA (2)
Controls Engineering Specialist (1)	4664	PHMSA (1)
Controls Engineering Admin* (1)	5540	PHMSA (1)
Electric Utility Equipment Operator	4348	FMCSA (2)
Equipment Mechanic I**	**4020**	**FMCSA (2A-ba)**
Equipment Mechanic II**	**4228**	**FMCSA (2A-ba)**
Equipment Repair Assistant**	**3316**	**FMCSA (2A-ba)**
Equipment Service Worker**	**3629**	**FMCSA (2A-ba)**
Field Coordinator -Customer Service (CS)*	4567	PHMSA (1)
Field Supervisor – CS*	4441	PHMSA (1)
Field Utility Specialist – CS	4109	PHMSA (1)
Field Utility Spec Trainee – CS	4029	PHMSA (1)
Fleet Maint Superintendent*/**	**5085**	**FMCSA (2A-ba)**
Fuel System Specialist**	**4460**	**PHMSA (3A)/FMCSA (ba)**
Gas Cathodic Protection Tech	4103	PHMSA (1)
Energy Resources Compliance Specialist	4754	PHMSA (1)
Gas Construction Coordinator*	5022	PHMSA (1)
Gas Leak Survey Specialist	4240	PHMSA (1)
Gas Measurement Specialist	4211	PHMSA (1)
Gas Measurement Supervisor*	4641	PHMSA (1)
Gas Measurement Trainee	4043	PHMSA (1)
Gas Meter & Supply Supervisor*	4679	PHMSA (1)
Gas System Crew Leader*	4508	PHMSA (3)/FMCSA
Gas System Equipment Operator	4297	PHMSA (3)/FMCSA
Gas System Inspector	4401	PHMSA
Gas System Superintendent*	5326	PHMSA (3)/FMCSA
Gas System Supervisor*/**	**4731**	**PHMSA (3A)/FMCSA (ba)**
Gas System Welder	4101	PHMSA (3)/FMCSA
Gas System Worker	4197	PHMSA (3)/FMCSA
Gas Tech Services Supervisor*	4801	PHMSA (1)
Heavy Equipment Operator I/II	3931/4034	FMCSA (2)
Heavy Equip Operator – Asphalt Distribution	4116	FMCSA (2)
Heavy Equipment Operator – SS	3953	FMCSA (2)
Intelligent Transportation System (ITS) Tech I	4573	FMCSA (2)

Position Title	Job Code	Applicable DOT Program (click here for Legend)
Intelligent Transportation System (ITS) Tech II	4753	FMCSA (2)
Lead Controls Engineering Specialist	4908	PHMSA (1)
Lead Gas Cathodic Protection Specialist*	4744	PHMSA (1)
Lead Tire Service Worker*	**3832**	**FMCSA (2A-ba)**
Lead Utility Locator*	4742	PHMSA (1)
Line Foreman*	4876	FMCSA (2)
Lineman	4442	FMCSA (2)
Lineman Apprentice I/II	4182/4296	FMCSA (2)
Lineman Apprentice III/IV	4311/4492	FMCSA (2)
Meter Maintenance/Irrigation Technician	3808	PHMSA (1)
Meter Reader	3720	PHMSA (1)
Parks & Commercial Facilities Maintenance Foreman*	4606	FMCSA (2)
Parks Equipment Mechanic	4122	FMCSA (2)
Parks Maintenance Leader*	**4007**	**FMCSA (2A-ba)**
Parks Maintenance Worker II	3842	FMCSA (ba) (2A)
Pavement Management Technician**	**4206**	**FMCSA (2A-ba)**
Sr Equipment Mechanic I/II	**4310/4695**	**FMCSA (2A-ba)**
Shop Foreman*	**4404**	**FMCSA (2A-ba)**
Shop Supervisor*	**4601**	**FMCSA (2A-ba)**
Solid Waste Collections Supervisor*/**	**4834**	**FMCSA (2A-ba)**
Solid Waste Equipment Operator I/II	3633/3835	FMCSA (2)
Solid Waste Equipment Service Assistant**	**3213**	**FMCSA (2A-ba)**
Solid Waste Mgmt Dept Director*/**	**5710**	**FMCSA (2A-ba)**
Solid Waste Foreman*	4143	FMCSA (2)
Solid Waste Routing Specialist	4173	FMCSA (2)
Solid Waste Safety & Training Rep	4674	FMCSA (2)
Solid Waste Services Representative	4017	FMCSA (ba) (2A)
Streetlight Technician I/II	4258/4507	FMCSA (2)
Streetlight Worker	3739	FMCSA (2)
Tire Service Worker	3630	FMCSA (2)
Traffic Operations Worker**	**3719**	**FMCSA (2A-ba)**
Traffic Operations Foreman I*	4178	FMCSA (2)
Transportation Field Operations Foreman*	4305	FMCSA (2)
Transportation Field Operations Foreman – Street Sweeper*	4362	FMCSA (2)
Transportation Field Operations Supervisor*/**	**4604**	**FMCSA (2A-ba)**
Transportation Field Operations Worker	3706	FMCSA (2)
Transportation Field Operations Worker–Road Hazard Response	3938	FMCSA (2)
Utilities Control Center Operator	3755	PHMSA (1)
Utilities Control Center Supervisor*	4627	PHMSA (1)
Utilities Distribution Controller	4135	PHMSA (1)
Utilities Distribution Shift Leader*	4496	PHMSA (1)
Utility Locator	4039	PHMSA (1)

Position Title	Job Code	Applicable DOT Program (click here for Legend)
Utility Locator Supervisor*	4402	PHMSA (1)
Utility Service Administrator*	5045	PHMSA (1)
Utility Service Field Supervisor*	4780	PHMSA (1)
Utility Service Specialist	4261	PHMSA (1)
Utility Service Worker	4018	PHMSA (1)
Wastewater (WW) Collection System Crew Leader*	4185	FMCSA (2)
WW Collection System Operator	3870	FMCSA (2)
WW Collection System Worker	3544	FMCSA (2)
Water Distribution Crew Leader*	4344	FMCSA (2)
Water Distribution Equip Operator	4108	FMCSA (2)
Water Distribution Worker I/II	3791/4000	FMCSA (2)
Water Plant (WP) Maintenance Specialist I (WW & WS)	3886	FMCSA (ba) (2A)
WP Maintenance Specialist II (WW & WS)	4119	FMCSA (ba) (2A)
WP Maintenance Specialist III (WW & WS)	4343	FMCSA (ba) (2A)
Welder**	**4395**	**FMCSA (2A-ba)**

*Incumbents are required to receive 60 minutes of training on alcohol misuse & 60 minutes of training on controlled substance use.

****Classification does not require CDL;** however, employee(s) has chosen to maintain CDL for work purposes.

APPENDIX C

URINE COLLECTION PERSONNEL & COLLECTION SITES, FORMS, EQUIPMENT & SUPPLIES USED IN DOT URINE COLLECTIONS

Urine Collection Personnel Requirements

1. Personnel who may collect urine specimens for DOT drug testing (§40.31).

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 this appendix (§40.33).

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

d. A person must not act as the collector for the employee being tested if he/she works 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.

2. Training requirements that collectors must meet (§40.33) - To be permitted to act as a collector in the DOT drug-testing program each collector must meet each of the requirements of this section:

a. Basic information. The collector must be knowledgeable about this part, the current " DOT Urine Specimen Collection Procedures Guidelines, " and DOT agency regulations applicable to the companies for whom the collector performs collections, and the collector must keep current on any changes to these materials. The DOT Urine Specimen Collection Procedures Guidelines document is available from ODAPC.

b. Qualification training. The collector 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 the completion of the qualification training under paragraph 2.b. of this section, the collector 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 the 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 a qualified collector who has demonstrated necessary knowledge, skills, and abilities by:

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

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

(c) 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 the collector must meet:

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

(3) If you become a collector on or after August 1, 2001, the collector must meet the requirements of paragraphs 2.b. and 2.c. of this section before performing collector functions.

e. Refresher training. No less frequently than every five years from the date on which the collector's satisfactorily completed the requirements of paragraphs 2.b. and 2.c. of this section, the collector must complete refresher training that meets all the requirements of paragraphs 2.b. and 2.c. of this section.

f. Error Correction Training. If the collector makes a mistake in the collection process that causes a test to be cancelled (i.*e.,* a fatal or uncorrected flaw), the collector 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 the collector's proficiency documented in writing by a person who meets the requirements of paragraph 2.c.(2) 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, the collector 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 the collector's 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. The collector must maintain documentation showing that the collector currently meet all requirements of this section. The collector 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.

3. Information provided by the DER to collectors (§40.35) - The company 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.

4. Other information on the role of collectors may be found (§40.35) – The collector can find other information on the role and functions of collectors in the following sections of the Part regulations:

§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.

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

1. Criteria for urine collection and where they may be collected (§40.41).

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

b. The collector operating a collection site must ensure that it meets the security requirements of §40.43.

c. The collector operating a collection site 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. The 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) The collection site 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 multi-stall 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 a multi-stall restroom is used either-

(a) 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

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

(3) No one but the employee may be present in the multi-stall 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.

2. Steps operators of collection sites must take to protect security and integrity of urine collections (§40.43).

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. The collector 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; Tape or otherwise secure shut any movable toilet tank top, or put bluing in the tank; Ensure that undetected access (e. g., through a door not in view) is not possible;

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

(6) 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, the collector must 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. The collector must take the following additional steps to ensure security during the collection process:

(1) To avoid distraction that could compromise security, the collector is 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)), the collector may conduct a collection for another employee.

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

(3) Ensure the collector is 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 the collector the specimen and when the collector seal the specimen, remain within the collection site.

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

e. The collector operating a collection site 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.

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

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

f. When operating a collection site, you must minimize the number of persons handling specimens.

3. Forms to be used to document a DOT urine collection (§40.45).

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.

b. The company must not use a non-Federal form or an expired Federal form to conduct a DOT urine collection. As a laboratory, C/TPA or other party that provides CCFs to employers, collection sites, or other customers, the company must not provide copies of an expired Federal form to these participants. The company must affirmatively notify these participants that they must not use an expired form (e.g., that beginning August 1, 2001, they may not use the old 7-part Federal CCF for DOT urine collections).

c. As a participant in the DOT drug-testing program, the company/collector is not permitted to modify or revise the CCF except as follows:

(1) The company/collector 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, phone 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 a company, 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. The company may use a C/TPAs address in place of its own, but must continue to include its name, telephone number, and fax number.

(3) The company may add the name of the DOT agency under whose authority the test occurred as part of the employer information.

(4) The collector 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.

d. 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.

e. The company may use an equivalent foreign-language version of the CCF approved by ODAPC. The company 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.

4. Company's use of CCF for non-Federal collections or non-Federal forms for DOT collections (§40.47).

a. The company is prohibited from using the CCF for non-Federal urine collections. The company is also prohibited from using non-Federal forms for DOT urine collections. Doing either subject's the company to enforcement action under DOT agency regulations.

b. 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.

c. The use of the non-Federal form is a "correctable flaw". The MRO, can correct the problem by following the procedures of §40.205(b)(2).

5. Materials used to collect urine specimens (§40.49) - For each DOT drug test, the company must use a collection kit meeting the requirements of 49 CFR Part 40.

6. Materials are used to send urine specimens to the laboratory (§40.51).

a. Except as provided in paragraph (b) of this section, the collector 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. The collector is not required to use a shipping container if a laboratory courier hand-delivers the specimens from the collection site to the laboratory.

Subpart E - Urine Specimen Collections

1. Preliminary steps in the collection process (§40.61) - The collector 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, the collector begins the testing process without undue delay, because an authorized company or employee representative is delayed in arriving.

(1) If the employee is also going to take a DOT alcohol test, the collector 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) The collector 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. The collector must see a photo ID issued by the company (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). The collector may not accept faxes or photocopies of identification. Positive identification by a company 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, the collector must provide his/her identification to the employee. The collector's identification must include name and employer's name, but does not have to include the collector's 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. The collector must also direct the employee to leave these garments and any briefcase, purse, or other personal belongings with the collector or in a mutually agreeable location. The collector must advise the employee that failure to comply with these directions constitutes a refusal to test.

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

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

(3) The collector 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) The collector 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. The employee must allow the collector to make this observation.

(5) If, the duties under paragraph (f)(4) of this section, the collector finds any material that could be used to tamper with a specimen, the collector must:

(a) 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

(b) 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. The collector 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.)

2. Steps collector must take in the collection process before the employee provides a urine specimen (§40.63) - The collector 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. Tell the employee not to wash his or her hands again until after delivering the specimen to you. Do 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 the collector or the employee, with both present, must unwrap or break the seal of the collection container. The collector must not unwrap or break the seal on any specimen bottle at this time. The collector 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 the collector 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 the collector nor anyone else may go into the room with the employee.

(2) The collector may set a reasonable time limit for voiding.

e. The collector 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 the collector detects such conduct, the collector 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). The collector 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. Collector must check for the following items when an employee presents a specimen (§40.65) The collector must check the following when the employee gives the collection container to the collector:

a. Sufficiency of specimen. The collector must check to ensure that the specimen contains at least 45 mL of urine.

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

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

(3) The collector should never combine urine collected from separate voids to create a specimen.

(4) The collector must discard any excess urine.

b. Temperature. The collector 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) The collector 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, the collector must mark the “Yes" box on the CCF (Step 2).

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

(5) If the specimen temperature is outside the acceptable range, the collector 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, the collector 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. The collector 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)), The collector 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. The collector 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), the collector 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, the collector 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. The collector 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 a specimen under the direct observation (see Sec. 40.191(a)(4)), you must discard any specimen the employee provided previously during the collection procedure. Then the collector must notify the DER as soon as possible.

4. When and how a direct observation collection is conducted (§40.67).

a. The company 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 the company that there was not an adequate medical explanation for the result; or

(2) The MRO reported to you that the original positive, adulterated, or substituted test result had to be cancelled because the test of the split specimen could not be performed.

b. The company 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. The collector must immediately conduct a collection under direct observation if:

(1) The collector is directed by the DER to do so (see paragraphs 4.a. and 4.c. of this section); or

(2) The collector 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. The company must:

(1) explain to the employee the reason for a directly observed collection under paragraph (a) or (b) of this section.

(2) explain to the employee the reason, if known, under this part for a directly observed collection under 4.c.(1) through 4.c.(3) of this section.

e. The collector must complete a new CCF for the directly observed collection.

(1) The collector must mark the "reason for test" block (Step 1) the same as for the first collection.

(2) The collector 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. The collector must ensure that the observer is the same gender as the employee. The collector 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. The collector, if someone else is to observe the collection (e.*g.,* in order to ensure a same gender observer) must verbally instruct that person to follow procedures at paragraphs 4.i. and 4.j. of this section. If the collector is the observer, the collector must follow these procedures.

i. The observer must watch the employee urinate into the collection container. Specifically, the observer is to watch the urine go from the employee's body into the collection container.

j. The observer not the collector must not take the collection container from the employee, but the observer must observe the specimen as the employee takes it to the collector.

k. The collector, when someone else has acted as the observer, the collector must include the observer's name in the '' Remarks'' line of the CCF (Step 2).

l. If the employee declines to allow a directly observed collection required or permitted under this section to occur, this is a refusal to test.

m. The collector, when he/she learns that a directly observed collection should have been collected but was not, the collector must inform the employer that is must direct the employee to have an immediate recollection under direct observation.

n. The collector, when he/she learns that a directly observed collection should have been collected but was not, the collector must inform the employer that it must direct the employee to have an immediate recollection under direct observation.

5. Criteria for conducting a monitored collection (§40.69)

a. The collector 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. The collector must ensure that the monitor is the same gender as the employee, unless the monitor is a medical professional (e.g., nurse, doctor, physician's assistant, technologist, or technician licensed or certified to practice in the jurisdiction in which the collection takes place). The monitor can be a different person from the collector and need not be a qualified collector.

c. The collector must, if someone else is to monitor the collection (e.g., in order to ensure a same gender monitor), verbally instruct that person to follow procedures at paragraphs (d) and (e) of this section. If the collector is also the observer, then he/she must follow these procedures.

d. The monitor must not watch the employee urinate into the collection container. If he/she hears 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. The monitor 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, the collector must note that person's name in the '' Remarks'' line of the CCF (Step 2).

g. If the employee being tested declines to permit a collection authorized under this section to be monitored, it is a refusal to test.

6. Collector preparation of a urine specimen (§40.71).

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

b. The collector must take the following steps, in order, after the employee brings the urine specimen to the collector. The collector 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) The collector, 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) The collector, 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) The collector, not the employee, must place and secure (i. *e.,* tighten or snap) the lids/ caps on the bottles.

(5) The collector, 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) The collector, not the employee, must then write the date on the tamper-evident bottle seals.

(7) The collector 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.
(8) The collector must discard any urine left over in the collection container after both specimen bottles have been appropriately filled and sealed. There is one exception to this requirement: the collector may use excess urine to conduct clinical tests (e.g., protein, glucose) if the collection was conducted in

conjunction with a physical examination required by a DOT agency regulation. Neither the collector nor anyone else may conduct further testing (such as adulteration testing) on this excess urine and the employee has no legal right to demand that the excess urine be turned over to the employee.

7. Completion of the collection process (§40.73).

a. The collector must do the following things to complete the collection process. The collector 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:

(a) 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.)

(b) Seal the container as appropriate.

(c) 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.

(d) 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. The collector or collection site 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.

8. DOT standards for urine collection kits.

The Collection Kit Contents:

a. Collection Container

(1) Single-use container, made of plastic, large enough to easily catch and hold at least 55 mL of urine voided from the body.

(2) Must have graduated volume markings clearly noting levels of 45 mL and above.

(3) Must have a temperature strip providing graduated temperature readings 32-38º C / 90-100º 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.

(4) 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.

(5) May be made available separately at collection sites to address shy bladder situations when several voids may be required to complete the testing process.

b. Plastic Specimen Bottles

(1) 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.

(2) Must have screw-on or snap-on caps that prevent seepage of the urine from the bottles during shipment.

(3) 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.

(4) 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.

(5) 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.

(6) Plastic material must be leach resistant.

c. Leak-resistant Plastic Bag

(1) 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.

(2) The sealing methodology must be such that once the compartments are sealed, any tampering or attempts to open either compartment will be evident.

d. 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.

e. Shipping Container

(1) 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).

(2) May be made available separately at collection sites rather than being part of an actual kit sent to collection sites.

(3) 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.

SPLIT SPECIMEN TESTS

Subpart H - Split Specimen Tests

1. Employee Requirements for Requesting A Test of A Split Specimen (§40.171).

a. The employee, when the MRO has notified him/her that they have a verified positive drug test or refusal to test because of adulteration or substitution, has 72 hours from the time of notification to request a test of the split specimen. The request may be verbal or in writing. If the employee makes this request to the MRO within 72 hours, the employee triggers the requirements of this section for a test of the split specimen.

b. Employee Request Procedures:

(1) If the employee has not requested a test of the split specimen within 72 hours, the employee 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) If the MRO concludes from the employee's information that there was a legitimate reason for the employee's failure to contact you within 72 hours, the MRO must direct that the test of the split specimen take place, just as the MRO would when there is a timely request.

c. When the employee makes a timely request for a test of the split specimen under paragraphs 1.a. and 1.b. of this section, the MRO must 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. The MRO must also document the date and time of the employee's request.

2. Responsibility for Payment for the Test of A Split Specimen (§40.173).

a. The company is 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. The company must not condition 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 the company's asks 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, the company must ensure that the test takes place in a timely manner, even though this means that you pay for it.

c. The company 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 company ensures that the testing is conducted as required and the results released appropriately.

3. What steps does the first laboratory take with a split specimen (§40.175).

a. The laboratory at which the primary and split specimen first arrived must check to see whether the split specimen is available for testing.

b. If the split specimen is unavailable or appears insufficient, the laboratory must then do the following:

(1) Continue the testing process for the primary specimen as the laboratory 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 the laboratory 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 about the cause of the unavailability.

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

d. When the laboratory receives written notice from the MRO instructing the laboratory to send the split specimen to another HHS-certified laboratory, the laboratory 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. The laboratory 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.

4. Second laboratory Procedures Regarding Split Specimen When Tested to Reconfirm the Presence of a Drug or Drug Metabolite (§40.177).

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

b. The laboratory 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, the laboratory must conduct validity tests in an attempt to determine the reason for being unable to reconfirm the presence of the drug(s)/metabolite(s). The laboratory should conduct the same validity tests as the laboratory 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, the laboratory may transmit the specimen or an aliquot of it to another HHS-certified laboratory that will conduct another reconfirmation test.

5. Second Laboratory Procedures Regarding Split Specimen When Tested to Reconfirm an Adulterated Test Result (§40.179).

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

6. Second Laboratory Procedures Regarding Split Specimen When Tested to Reconfirm a Substituted Test Result (§40.181).

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

7. Information Laboratories May Report to MROs Regarding Split Specimen Results (§40.183).

a. The laboratory responsible for testing the split specimen 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 the laboratory checked 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. The laboratory’s certifying scientist must enter his/her name, sign, and date the CCF.

8. Methods and Procedures the Laboratory must Report for Split Specimen Results (§40.185).

a. The laboratory testing the split specimen must report laboratory results directly, and only, to the MRO at his or her place of business. The laboratory must not report results to or through the DER or another service agent (e.g., a C/TPA).

b. The laboratory 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. The laboratory 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.

9. MRO Responsibility With Regard to Disposition of Split Specimen Laboratory Results (§40.187) - The MRO must take the following actions when a laboratory reports the following results of split specimen tests:

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

b. 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.

c. 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.

d. 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.

e. Failed to Reconfirm: Specimen Results Invalid.

(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.

f. Failed to Reconfirm: Split Specimen Adulterated.

(1) Contact the employee and inform the employee that the laboratory has determined that his or her split specimen is adulterated.

(2) Follow the procedures of Sec. 40.145 to determine if there is a legitimate medical explanation for the laboratory finding of adulteration.

(3) If the MRO determines that there is a legitimate medical explanation for the adulterated test result, report to the DER and the employee that the test is cancelled. Using the format in Appendix D to this part, notify ODAPC of the result.

(4) If the MRO determines that there is not a legitimate medical explanation for the adulterated test result, take the following steps:

(a) Report the test to the DER and the employee as a verified refusal to test. Inform the employee that he or she has 72 hours to request a test of the primary specimen to determine if the adulterant found in the split specimen also is present in the primary specimen.

(b) Except that the request is for a test of the primary specimen and is being made to the laboratory that tested the primary specimen, follow the procedures of Sections. 40.153, 40.171, 40.173, 40.179, and 40.185.

(c) The laboratory that tests the primary specimen to reconfirm the presence of the adulterant found in the split specimen, report your result to the MRO on a photocopy (faxed, mailed, scanned, couriered) of Copy 1 of the CCF.

(d) If the test of the primary specimen reconfirms the adulteration finding of the split specimen the MRO must report the test result as a refusal as provided in Sec. 40.187(a)(2).

(e) If the test of the primary specimen fails to reconfirm the adulteration finding of the split specimen the MRO can cancel the test. Follow the procedures of paragraph (e) of this section in this situation.

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

(h) 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.

10. Additional Information Concerning Split Specimens can be found in this regulation (§40.189).

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.

11. 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).

APPENDIX D

DRUG TESTING LABORATORY GUIDANCE

Subpart F-Drug Testing Laboratories

1. Type of laboratories that may be used for DOT drug testing (§40.81).

a. A drug testing laboratory located in the U. S. is permitted to participate in DOT drug testing only if they are certified by HHS under the National Laboratory Certification Program (NLCP) for all testing required under this part.

b. A drug testing laboratory located in Canada or Mexico which is not certified by HHS under the NLCP, may be permitted to participate in DOT drug testing only if:

(1) The DOT, based on a written recommendation from HHS, has approved the laboratory as meeting HHS laboratory certification standards or deemed the 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. A laboratory participating in the DOT drug testing program must comply with the requirements of this part. They 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 the laboratory is in noncompliance with this part, they could be subject to PIE proceedings under Subpart R of this part. If the Department issues a PIE with respect to the laboratory then they are ineligible to participate in the DOT drug testing program even if they continue to meet the requirements of paragraph a or b of this section.

2. Laboratories processing of incoming specimens (§40.83) – The laboratory must do the following:

a. The laboratory is authorized to receive only the laboratory copy of the CCF. The laboratory is not authorized to receive other copies of the CCF nor any copies of the alcohol testing form.

b. The laboratory must comply with applicable provisions of the HHS Guidelines concerning accessioning and processing urine drug specimens.

c. The laboratory 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 the laboratory finds a specimen meeting the criteria of paragraph (c) of this section, they must document the findings and stop the testing process. Report the result in accordance with §40.97(a)(3).

e. The laboratory must inspect each CCF for the presence of the collector's signature on the certification statement in Step 4 of the CCF. Upon finding that the signature is omitted, document the flaw and continue the testing process.

(1) In such a case, the laboratory must retain the specimen for a minimum of 5 business days from the date on which the laboratory initiated action to correct the flaw.

(2) The laboratory must then attempt to correct the flaw by following the procedures of §40.205(b)(1).

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

f. If the laboratory determines that the specimen temperature was not checked and the "Remarks" line did not contain an entry regarding the temperature being outside of range, the laboratory must then attempt to correct the problem by following the procedures of §40.208.

(1) In such a case, the laboratory must continue efforts to correct the problem for five business days, before reporting the result.

(2) When the laboratory has obtained the correction, or five business days have elapsed, report the result in accordance with §40.97(a).

g. If the laboratory determines that a CCF that fails to meet the requirements of 40.45(a) (e.g., a non-Federal form or an expired Federal form) was used for the collection, the laboratory must attempt to correct the use of the improper form by following the procedures of 40.205(b)(2).

(1) In such a case, the laboratory must retain the specimen for a minimum of 5 business days from the date on which the laboratory initiated action to correct the problem.

(2) During the period August 1 - October 31, 2001, the laboratory is not required to reject a test conducted on an expired Federal CCF because this problem is not corrected. Beginning November 1, 2001, if the problem(s) is not corrected, the laboratory must reject the test and report the result in accordance with §40.97(a)(3).

h. If the CCF is marked indicating that a split specimen collection was collected and if the split specimen does not accompany the primary, has leaked, or is otherwise unavailable for testing, the laboratory 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 re-designated (i.*e.,* Bottle B is re-designated as Bottle A, and vice-versa) if:

(a) 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

(b) The primary specimen is labeled as Bottle B, and the split specimen as Bottle A; or

(c) 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

(d) 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 1.g. of this section, the laboratory shall mark through the " A" and write " B, " then initial and date the change. A corresponding change shall be made to the other bottle by marking through the " B" and writing " A " and initialing and dating the change.

i. A notation shall be made on Copy 1 of the CCF (Step 5a) and on any laboratory internal chain of custody documents, as appropriate, for any fatal or correctable flaw.

3. Drugs that the laboratories may test for under DOT (§40.85) – The laboratory must test for the following five drugs or classes of drugs in a DOT drug test. The laboratory must not test " DOT specimens" for any other drugs.

a. Marijuana metabolites

b. Cocaine metabolites

c. Opiate metabolites

d. 6-Acetylmorphine (6-AM)*

e. Phencyclidine (PCP)

f. Amphetamines/Methamphetamines

g. MDMA (Ecstacy)*

*As of October 1, 2010 DOT expanded drug testing panel to include 6-AM and MDMA

4. Cutoff concentrations for initial and confirmation tests (§40.87).

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

Initial test analyte	Initial test cutoff concentration	Confirmatory test analyte	Confirmatory test cutoff concentration
Marijuana metabolites	50 ng/mL	THCA[1]	15 ng/mL.
Cocaine metabolites	150 ng/mL	Benzoylecgonine	100 ng/mL.
Opiate metabolites			
Codeine/Morphine[2]	2000 ng/mL	Codeine	2000 ng/mL.
		Morphine	2000 ng/mL.
6–Acetylmorphine	10 ng/mL	6–Acetylmorphine	10 ng/mL.
Phencyclidine	25 ng/mL	Phencyclidine	25 ng/mL.
Amphetamines[3]			
AMP/MAMP[4]	500 ng/mL	Amphetamine	250 ng/mL.
		Methamphetamine[5]	250 ng/mL.
MDMA[6]	500 ng/mL	MDMA	250 ng/mL.
		MDA[7]	250 ng/mL.
		MDEA[8]	250 ng/mL

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

b. On an initial drug test, the laboratory must report a result below the cutoff concentration as negative. If the result is at or above the cutoff concentration, the laboratory must conduct a confirmation test.

c. On a confirmation drug test, the laboratory must report a result below the cutoff concentration as negative and a result at or above the cutoff concentration as confirmed positive.

d. The laboratory must report quantitative values for morphine or codeine at15000 ng/mL or above.

e. On a 6–AM confirmed positive result:

(1) When a 6–AM confirmed positive result is reported and morphine for that specimen is not reported at or above the 2000 per ng/mL confirmed positive cutoff, you must confer with the MRO to determine if there was confirmed morphine below 2000 ng/mL.

(2) If morphine was not confirmed below 2000 ng/mL, you and the MRO must determine whether further testing is needed to quantify the amount of morphine concentration present.

(3) If you find no detectable morphine at LOD upon further testing, you must report that fact to ODAPC immediately.

5. Validity testing and requirements of laboratories required to conduct such testing (§40.89).

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. The laboratory is authorized to conduct validity testing.

6. Types of validity tests that laboratories must conduct on primary specimens (§40.91) – The laboratory must conduct validity testing in accordance with the requirements of this section under §40.89.

a. The laboratory must test each primary specimen for creatinine. The laboratory must also determine its specific gravity if you find that the creatinine concentration is less than 20 ng/mL.

b. The laboratory must measure the pH of each primary specimen.

c. The laboratory must test each primary specimen to determine if it contains substances that may be used to adulterate the specimen. The laboratory 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 the laboratory suspects the presence of an interfering substance/adulterant that could make a test result invalid, but are unable to identify it (e.g., a new adulterant), the laboratory must, as the first laboratory, send the specimen to another HHS certified laboratory that has the capability of doing so.

e. If the laboratory identifies a substance in a specimen that appears to be an adulterant, but which is not listed in current HHS requirements or guidance, the laboratory must report the finding in writing to ODAPC and the

Division of Workplace Programs, HHS, within three business days. The laboratory must also complete testing of the specimen for drugs, to the extent technically feasible.

f. The laboratory must conserve as much as possible of the specimen for possible future testing.

7. Criteria for laboratories to establish that a specimen is dilute or substituted (§40.93).

a. The laboratory 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. The laboratory must consider the primary specimen to be substituted if the creatinine concentration is less than or equal to 5 ng/mL and the specific gravity is less than or equal to 1.001 or greater than or equal to 1.020.

8. Criteria for laboratories to establish that a specimen is adulterated (§40.95).

a. The laboratory 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 the determination under paragraph (a) of this section the laboratory apply the criteria in current HHS requirements or specimen validity guidance.

9. Laboratories Reporting Format and Information (§40.97).

a. The laboratory must report the results for each primary specimen tested as one or more 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 remark(s); or

(8) Invalid result, with remark(s).

b. The laboratory must report laboratory results directly, and only, to the MRO at his or her place of business. The laboratory must not report results to or through the DER or a service agent (e.*g.,* C/TPA).

(1) Negative results: lab 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 they may provide the laboratory results report electronically (i.*e.,* computer data file).

(a) If the laboratory elects to provide the laboratory results report, they must include the following elements, as a minimum, in the report format:

(A) Laboratory name and address;
(B) Employer's name (you may include I. D. or account number;
(C) Medical review officer's name;
(D) Specimen I. D. number;

(E) Donor's SSN or employee I. D. number, if provided;
(F) Reason for test, if provided;
(G) Collector's name and telephone number;
(H) Date of the collection;
(I) Date received at the laboratory;
(J) Date certifying scientist released the results;
(K) Certifying scientist's name
(L) Results (e. *g.,* positive, adulterated) as listed in paragraph 9.a. of this section; and
(M) Remarks section, with an explanation of any situation in which a correctable flaw has been corrected.

(b) The laboratory may release the laboratory results report may be released only after review and approval by the certifying scientist. It must reflect the same test result information as contained on the CCF signed by the certifying scientist. The information contained in the laboratory results report may not contain information that does not appear on the CCF.

(c) The results report may be transmitted through any means that ensures accuracy and confidentiality. 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: 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 the laboratory may provide the electronic laboratory results report following the format and procedures set forth in paragraphs (b)(1)(a) and (b) of this section.

c. In transmitting laboratory results to the MRO, 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. The laboratory must transmit test results to the MRO in a timely manner, preferably the same day that review by the certifying scientist is completed.

e. The laboratory must provide quantitative values for confirmed positive drug, adulterated, and substituted test results to the MRO when the MRO requests you to do so in writing. The MRO's request may either be a general request covering all such results you send to the MRO or a specific case-by-case request.

f. The laboratory must provide quantitative values for confirmed opiate results for morphine or codeine at15000 ng/mL or above, even if the MRO has not requested quantitative values for the test result.

10. Criteria for laboratory retention of specimens after testing (§40.99).

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

b. The laboratory 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 company, or a DOT agency may request in writing that the laboratory retain a specimen for an additional period of time (e.g., for the purpose of preserving evidence for litigation or a safety investigation). If the laboratory receives such a request, they must comply with it. If the laboratory does not receive such a request, they may discard the specimen at the end of the year.

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

e. The laboratory testing the split specimen must meet the requirements of paragraphs 10.a. through 10.d. of this section with respect to the split specimen.

11. Criteria for laboratory and MRO relationship (§40.101).

a. The laboratory 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. The laboratory 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.

12. Requirements for submitting blind specimens to a laboratory (§40.103).

a. The company or C/TPA with an aggregate of 2000 or more DOT-covered employees the company must send blind specimens to laboratories utilized. If the company has an aggregate of fewer than 2000 DOT-covered employees, the company is not required to provide blind specimens.

b. To each laboratory to which the company or C/TPA sends at least 100 specimens in a year, the company must transmit a number of blind specimens equivalent to one percent of the specimens the company or C/TPA sends to that laboratory, up to a maximum of 50 blind specimens in each quarter (i.e., January-March, April- June, July-September, October-December). C/TPA must apply this percentage to the total number of DOT-covered employees' specimens send to the laboratory. 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 submitted 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 the company submits 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. The company must ensure that each blind specimen is indistinguishable to the laboratory from a normal specimen.

(1) The company 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) The company 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) The company must ensure that all blind specimens include split specimens.

13. Criteria for laboratory that reports result different from that expected for a blind specimen (§ 40.105).

a. The company, MRO, or C/TPA who submits a blind specimen, and if the result reported to the MRO is different from the result expected, the company must investigate the discrepancy.

b. If the unexpected result is a false negative, the company 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, the company 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. The company must also notify ODAPC of the discrepancy. ODAPC will notify HHS who will take appropriate action.

14. Criteria for laboratory inspections (§40.107).

a. The laboratory 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.

15. Documentation the laboratory shall maintain and length of retention (§40.109).

a. The laboratory must retain all records pertaining to each employee urine specimen for a minimum of two years.

b. The laboratory must also keep for two years company-specific data required in §40.111.

c. Within the two-year period, the MRO, the employee, the company, 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 the laboratory receives such a request, the laboratory must comply with it. If the laboratory does not receive such a request, the laboratory may discard the records at the end of the two-year period.

16. Criteria for when and how a laboratory may disclose statistical summaries and other information it maintains (§40.111).

a. The laboratory must transmit an aggregate statistical summary, by company, of the data listed in paragraph 18 of this part to the company 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, the laboratory must not send a summary if the company 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 company requests a summary in response to an inspection, audit, or review by a DOT agency, the laboratory must provide it unless the company had fewer than five aggregate test results. In that case, the laboratory must send the company a report indicating that not enough testing was conducted to warrant a summary. The laboratory may transmit the summary or report by hard copy, fax, or other electronic means.

c. The laboratory must also release information to appropriate parties as provided in §40.329 and 40.331.

17. Information concerning laboratories may be found in 49 CFR Part 40 regulations (§40.111).

a. More information concerning laboratories is 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.

18. 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/TPA Identification: (where applicable; name and address)

1. Number of specimen results reported: (total number) by test types:
   (a) Pre-employment testing: (number)
   (b) Post-accident testing: (number)
   (c) Random testing: (number)
   (e) Reasonable suspicion/cause testing: (number)
   (f) Return-to-duty testing: (number)
   (g) Follow-up testing: (number)
   (h) 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)

APPENDIX E

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City of Mesa
Observed Behavior – Reasonable Cause Form

Employee Name:_____ Employee ID Number:_____

Date of Observation: _____ Time From _____am/pm Time To _____am/pm

Location:_____

Department / Accounting Information: Fund _____ Subfund _____ Appropriation Code_____
Dept _____ Unit _____ Activity _____ SubActivity _____ Object Code _____

Presence of Drug Odor and/or Paraphernalia (specify) _____

Presence of Alcohol Odor and/or Alcohol Itself or Containers (specify) _____

Appearance:
☐ Normal ☐ Flushed ☐ Puncture Marks/Tracks
☐ Disheveled ☐ Bloodshot Eyes ☐ Inappropriate Wearing of Sunglasses
☐ Dilated/Constricted Pupils ☐ Profuse Sweating
☐ Tremors ☐ Dry-Mouth Symptoms ☐ Runny Nose/Sores
☐ Other _____

Behavior/ Speech:
☐ Normal ☐ Incoherent ☐ Slurred
☐ Confused ☐ Slowed ☐ Whispering
☐ Other _____

Awareness:
☐ Normal ☐ Confused ☐ Mood Swings ☐ Euphoria
☐ Lethargic ☐ Lack of Coordination ☐ Paranoid ☐ Disoriented
☐ Other _____

Motor Skills/ Balance:
☐ Normal ☐ Swaying ☐ Falling ☐ Staggering
☐ Other _____

Walking/ Turning:
☐ Normal ☐ Swaying ☐ Arms raised for Balance
☐ Stumbling ☐ Falling ☐ Reaching for Support
☐ Other _____

Other Observed Actions/Behavior (specify): _____

I certify that I have had training in recognition of alcohol and controlled substance misuse and that to the best of my judgment adequate reasonable suspicion exists sufficient to require the above employee to undergo testing for alcohol and controlled substances. The observations, as documented above were made and witnessed by:

_____ _____ _____
Trained Supervisor's Name (printed) Signature Date

_____ _____ _____
Second Trained Supervisor's Name (printed) Signature Date

Employee transported to collection site by: _____ Time transported: _____am/pm

This document must be presented and signed by the witnesses within 24 hours of the observed behavior or before the results of the test are released, whichever is earlier. (49 CFR 382.307[F])

APPENDIX F

ACKNOWLEDGMENT AND AGREEMENT
WITH RESPECT TO DRUG AND ALCOHOL TESTING

I, the undersigned employee hereby certify that I have been furnished with a copy of the DOT Alcohol and Drug Testing Program, including its Employee Assistance Program, and that I have read and understand same. I further certify that I have been provided with informational material, education and training on the dangers and problems of drug and alcohol misuse.

- ❑ 1. The designated person to answer questions about the materials.
- ❑ 2. The employees subject to these rules.
- ❑ 3. Specific information concerning prohibited employee conduct..
- ❑ 4. Circumstances under which an employee will be tested.
- ❑ 5. Test procedures, employee protection and integrity of the testing processes, and safeguarding the validity of the test.
- ❑ 6. The requirement that tests are administered in accordance with the rules.
- ❑ 7. An explanation of what will be considered a refusal to submit to a test and the consequences.
- ❑ 8. Sufficient information about the safety-sensitive functions and period of the workday that compliance is required.
- ❑ 9. The consequences for violating these rules and procedures including removal from safety-sensitive functions.
- ❑ 10. The consequences for employees found to have an alcohol concentration of 0.02 or greater but less than 0.04.
- ❑ 11. Information on the affects of alcohol and controlled substances use.
- ❑ 12. City of Mesa's DUI Discipline Policy – Management Policy #347

If Applicable:

- ❑ 13. Certified Medical Examiner and CDL Medical exam.
- ❑ 14. CDL Regulations/Statutes/Policy & Procedures

I am fully aware, and agree that I may be discharged or otherwise disciplined for any violation by me of said DOT Alcohol and Drug Policy, for any failure or refusal to provide urine and/or breath specimens when requested by my employer, for the failure or refusal to identify and certify same, for the failure to cooperate with the forms and other documents, and/or for any other Alcohol and Drug Testing Program requirement.

Executed this the _____ day of _____, 20_____.

_____ _____
Employee Name (Please Print) **Employee ID or Social Security No.**

_____
Employee Signature

Added to DOT Random Pool: FMCSA Session _____ / PHMSA Session _____
Initials/Date: _____ Dept#: _____