SUBSTANCE ABUSE

AND

ALCOHOL MISUSE PREVENTION PLAN

EMPLOYER NAME:

THIS PLAN HAS BEEN DEVELOPED FOR COMPLIANCE WITH UNITED STATES DEPARTMENT OF TRANSPORTATION TITLE 49 CODE OF FEDERAL REGULATION (CFR), PART 40 "PROCEDURES FOR TRANSPORTATION WORKPLACE DRUG AND ALCOHOL TESTING PROGRAMS" AND PART 382, "CONTROLLED SUBSTANCES AND ALCOHOL USE AND TESTING"

THIS POLICY WAS IMPLEMENTED ON _____

PROVIDED BY CENTRAL DRUG SYSTEM, INC ("CDS")
16560 HARBOR BLVD., SUITE A, FOUNTAIN VALLEY, CA 92708
(714) 418-0130 FAX (714) 418-0137

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SUBSTANCE ABUSE AND ALCOHOL MISUSE PREVENTION PLAN

1. Introduction

The Omnibus Transportation Employee Testing Act of 1991 required alcohol and drug testing of safety-sensitive employees in the aviation, motor carrier, railroad, and mass transit industries. The U.S. Department of Transportation (DOT) published rules mandating anti-drug and alcohol misuse prevention programs in February 1994. The rules also expanded and supplemented existing drug testing rules published in November 1988 that mandated drug testing of aviation, interstate motor carrier, railroad, pipeline, and commercial marine employees.

The DOT operating administrations' (Federal Aviation Administration, Federal Motor Carrier Safety Administration, Federal Railroad Administration, Federal Transit Administration, and the Pipeline and Hazardous Material Safety Administration) rules require that employers conduct drug testing according to provisions of 49 CFR Part 40, "Procedures for Transportation Workplace Drug Testing Programs," Final Rule, published in the Federal Register on December 19, 2000 (65 FR 79462), effective August 1, 2001, together with subsequent technical amendments. Previously published rules, amendments, interpretations, and guidelines are no longer in effect.

The Federal Motor Carrier Safety Administration (FMCSA) directs employers subject to its regulations to promulgate a policy on the misuse of alcohol and use of controlled substances (382.601). FMCSA also specifies that drug and alcohol testing procedures must be in accordance with 49 CFR Part 40, Procedures for Transportation Workplace Drug and Alcohol Testing Programs.

Drug use is a serious problem in our society. The 2003 National Survey on Drug Use and Health conducted by the Department of Health and Human Services (HHS) indicated that 19.5 million individuals 12 years and older were current illicit drug users. Of the 16.7 million individuals 18 years and older (who were current drug users), 12.4 million (74.3 percent) were employed either full or part time.

The survey also indicated that of the 119 million drinkers in the country, 54 million were binge drinkers and 16.1 million were heavy drinkers. Another recent HHS study compared the various costs to businesses, society, and our health care system and estimated the 1995 cost at 276 billion dollars.

A review of drug testing data shows that the programs for drug and alcohol testing directed by Federal regulations have had substantial impact. Drug testing positive rates have declined from a high of 18 percent in 1988 to less than 2 percent in 2004. Prevention and deterrence are key to a safer workplace.

1.1 Philosophy.

1.1.1 Drug Abuse is a Serious Problem.

The Employer recognizes that drug abuse or use of illegal drugs and alcohol misuse in today's society is a very serious problem which has found its way into the workplace. We also recognize the significant threat that a drug or alcohol impaired driver working in the transportation industry can pose to co-workers and to the general public.

1.1.2 Federal Response to Drug and Alcohol Abuse Problems.

In order to address the safety threat presented by the problem of drug abuse and alcohol misuse in the transportation industry, the Department of Transportation (DOT) and the Federal Motor Carrier Safety Administration (FMCSA) have established extensive regulations requiring drug ("drug(s)" and "controlled substance(s)" mean the same thing in this plan) and alcohol testing under certain circumstances.

1.1.3 This Employer's Response.

In light of this, the Employer has adopted this Substance Abuse and Alcohol Misuse Prevention Plan ("This Plan") to specify the circumstances under which drug and alcohol testing may be required, the procedures for conducting such testing and the methods and procedures for complying with the requirements of DOT/FMCSA regulations. The Employer must comply with all DOT/FMCSA regulations which require affirmative actions to eliminate the impact of abuse of drugs and misuse of alcohol in the workplace.

1.1.4 Purpose of Plan. (§382.101)

The purpose of this plan is to deter drug abuse and alcohol misuse in the transportation industry, reduce accidents, fatalities, injuries and property damage that result from drug abuse and alcohol misuse. This Plan has been developed in compliance with existing federal regulations in a manner which insures accurate and reliable test results. The term "Plan" and "Policy" has the same meaning in this document.

1.1.5 Procedures to Respect Privacy.

This Plan contains procedures designed to recognize and respect the dignity and privacy of our safety sensitive employees ("employee" and "driver" mean the same thing in this Plan). Within this Plan is information for employee access to an appropriate Employee Assistance Program ("EAP") designed to help those drivers wishing to obtain treatment for drug abuse and alcohol misuse. In addition, this Plan contains elements for educating drivers about the consequences of drug abuse and alcohol misuse.

1.1.6 This Employer's Independent Policies.

Policies and procedures which are based on the Employer's own authority, independent of the federal regulations contained in Title 49 CFR Parts 40 and 382 are contained in a separate document as indicated in Exhibit A.

1.2 Preemption Provisions. (§382.109)

1.2.1 Preemption of State and Local Laws.

Except as provided in paragraph 1.2.2, the federal regulations preempt any State or local law, rule, regulation, or order to the extent that:

1.2.1.1 Compliance with both the State or local requirement and this part is not possible; or

1.2.1.2 Compliance with the State or local requirement is an obstacle to the accomplishment and execution of any requirement in this part.

1.2.2 Limit of Preemption.

Part 382 is not to be construed to preempt provisions of State criminal law that impose sanctions for reckless conduct leading to actual loss of life, injury, or damage to property, whether the provisions apply specifically to transportation employees, employers, or the general public.

1.3 Definitions. (§40.3, 382.107)

1.3.1 Actual Knowledge

Means actual knowledge by an employer that a driver has used alcohol or controlled substances based on the employer's direct observation of the employee, information provided by the driver's previous employer(s), a traffic citation for driving a CMV while under the influence of alcohol or controlled substances or an employee's

admission of alcohol or controlled substance use, except as provided in Section 2.10. Direct observation as used in this definition means observation of alcohol or controlled substance use and does not include observation of employee behavior or physical characteristics sufficient to warrant reasonable suspicion testing under Section 3.4.

1.3.2 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.

1.3.3 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 ("PIE"), an organization having the same or similar management, ownership, or principal employees as the service agent concerning whom a public interest exclusion is in effect is regarded as an affiliate. This definition is used in connection with the public interest exclusion procedures of Subpart R of 49 CFR Part 40.

1.3.4 Air Blank

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

1.3.5 Alcohol

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

1.3.6 Alcohol Concentration (or Content)

The alcohol in a volume of breath expressed in terms of grams of alcohol per 210 liters of breath as indicated by a breath test under 49 CFR Part 40.

1.3.7 Alcohol Confirmation Test

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

1.3.8 Alcohol Screening Device (ASD)

A breath or saliva device, other than an EBT, that is approved by the National Highway Traffic Safety Administration (NHTSA) and placed on a conforming products list (CPL) for such devices.

1.3.9 Alcohol Screening Test

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

1.3.10 Alcohol Testing Site

A place where employees present themselves for the purpose of providing breath or saliva for an alcohol test.

1.3.11 Alcohol Use

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

1.3.12 Blind Specimen or Blind Performance Test Specimen

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

1.3.13 Breath Alcohol Technician (BAT)

A person who instructs and assists employees in the alcohol testing process and operates an evidential breath testing device.

1.3.14 Cancelled Test

A drug or alcohol test that has a problem identified that cannot be or has not been corrected, or which 49 CFR Part 40 otherwise requires to be cancelled. A cancelled test is neither a positive nor a negative test.

1.3.15 Chain of Custody

The procedure used to document the handling of the urine specimen from the time the employee gives the specimen to the collector until the specimen is destroyed. This procedure uses the Federal Drug Testing Custody and Control Form (CCF).

1.3.16 Collection Container

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

1.3.17 Collection Site

A place where employees present themselves for the purpose of providing a urine specimen for a drug test.

1.3.18 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.

1.3.19 Commerce

1.3.19.1 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; and

1.3.19.2 Trade, traffic, and transportation in the United States which affects any trade, traffic, and transportation described in paragraph 1.3.19.1.

1.3.20 Commercial Motor Vehicle (CMV)

A motor vehicle or combination of motor vehicles used in commerce to transport passengers or property if the motor vehicle:

1.3.20.1 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

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

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

1.3.20.4 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 and which require the motor vehicle to be placarded under the Hazardous Materials Regulations (49 CFR Part 172, subpart F).

1.3.21 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.

1.3.22 Confirmation (or Confirmatory) Validity Test

A second test performed on a urine specimen to further support a validity test result.

1.3.23 Confirmed Drug Test

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

1.3.24 Consortium/Third-Party Administrator (C/TPA)

A service agent that provides or coordinates one or more drug and/or alcohol testing services to DOT-regulated employers. C/TPAs typically provide or coordinate the provision of a number of such services and 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 (e.g., having a combined random testing pool). C/TPA's are not "employers" for purposes of 49 CFR Part 40.

1.3.25 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.

1.3.26 Controlled Substances

Marijuana, cocaine, amphetamines, phencyclidine (PCP), and opiates.

1.3.27 Designated Employer Representative (DER)

An employee identified by the employer as able to receive communications and test results from service agents and who is authorized to take immediate action(s) to remove employees from safety-sensitive duties and to make required decisions in the testing and evaluation processes. The individual must be an employee of the company. Service Agents cannot serve as DERs.

1.3.28 Dilute Specimen

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

1.3.29 Disabling Damage

Damage which precludes departure of a motor vehicle from the scene of the accident in its usual manner in daylight after simple repairs.

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

1.3.29.2 Exclusions

1.3.29.2.1 Damage which can be remedied temporarily at the scene of the accident without special tools or parts.

1.3.29.2.2 Tire disablement without other damage even if no spare tire is available.

1.3.29.2.3 Headlight or tail light damage.

1.3.29.2.4 Damage to turn signals, horn, or windshield wipers which make them inoperative.

1.3.30 DOT, The Department, DOT Agency

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

1.3.31 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.

1.3.32 Drugs

The drugs for which tests are required under 49 CFR Part 40 and DOT agency regulations are marijuana, cocaine, amphetamines, phencyclidine (PCP), and opiates.

1.3.33 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 49 CFR Part 40, 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 (HHS).

1.3.34 Employer

A person or entity employing one or more employees (including an individual who is self-employed) that is subject to DOT agency regulations requiring compliance with this part. The term means the entity responsible for overall implementation of DOT drug and alcohol program requirements, including individuals employed by the entity who take personnel actions resulting from violations of this part and any applicable DOT agency regulations. Service agents are not employers for the purposes 49 CFR Part 40.

1.3.35 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.

1.3.36 Evidential Breath Testing Device (EBT)

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

1.3.37 Health and Human Services (HHS)

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

1.3.38 Initial Drug Test

The test used to differentiate a negative specimen from one that requires further testing for drugs or drug metabolites.

1.3.39 Initial Validity Test

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

1.3.40 Laboratory

Any US 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. (The HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs are available on the internet at http://www.health.org/workpl.htm or from the Division of Workplace Programs, 1 Choke Cherry Road, Room 2-1035, Rockville, MD 20857).

1.3.41 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.

1.3.42 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.

1.3.43 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 49 CFR Part 40.

1.3.44 Performing (a Safety-Sensitive Function)

A driver is considered to be performing a safety-sensitive function during any period in which he or she is actually performing, ready to perform, or immediately available to perform any safety-sensitive functions.

1.3.45 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.

1.3.46 Positive Rate

The number of positive results for random controlled substances tests conducted under Part 382 plus the number of refusals of random controlled substances tests required by Part 382, divided by the total of random controlled substances tests conducted under Part 382 plus the number of refusals of random tests required by Part 382.

1.3.47 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, or video).

1.3.48 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 49 CFR Part 40 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, or video).

1.3.49 Refusal to Submit (to an Alcohol or Controlled Substances Test) when a driver:

1.3.49.1 Fails to appear for any test (except a pre-employment test) within a reasonable time, as determined by the employer, consistent with applicable DOT agency regulations, after being directed to do so by the employer. This includes the failure of an employee (including an owner-operator) to appear for a test when called by a C/TPA (paragraph 6.1.1);

1.3.49.2 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 Section 6.2) a pre-employment test is not deemed to have refused to test;

1.3.49.3 Fails to provide a urine specimen for any drug test required by this part or DOT agency regulations. An employee who does not provide a urine specimen because he or she has left the testing site before the testing process commences (Section 6.2) for a pre-employment test is not deemed to have refused to test;

1.3.49.4 In the case of a directly observed or monitored collection in a drug test, fails to permit the observation or monitoring of the driver's provision of a specimen (see paragraph 6.4.12 and 6.5.7);

1.3.49.5 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 paragraph 10.2.4.2);

1.3.49.6 Fails or declines to take a second test the employer or collector has directed the driver to take;

1.3.49.7 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 paragraph 10.2.3. 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;

1.3.49.8 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); or

1.3.49.9 Is reported by the MRO as having a verified adulterated or substituted test result.

1.3.50 Safety Sensitive Employee (Driver)

1.3.50.1 Safety Sensitive Employee means any person (driver) who operates a commercial motor vehicle in commerce in any State, and is subject to:

1.3.50.1.1 The commercial driver's license (CDL) requirements of Part 383;

1.3.50.1.2 The Licencia Federal de Conductor (Mexico) requirements; or

1.3.50.1.3 The commercial driver's license (CDL) requirements of the Canadian National Safety Code.

1.3.50.2 An employer who employs himself/herself as a driver must comply with both the requirements in this part that apply to employers and the requirements in this part that apply to drivers. An employer who employs only himself/herself as a driver shall implement a random alcohol and controlled substances testing program of two or more covered employees in the random testing selection pool.

1.3.50.3 The only exemptions from this plan are CMV drivers:

1.3.50.3.1 Required to comply with the alcohol and/or controlled substances testing requirements of Parts 653 and 654;

1.3.50.3.2 Those granted a waiver from the requirements of this program; or

1.3.50.3.3 Those who are exempt from the requirements of Part 383.

1.3.51 Safety-Sensitive Function

Means 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. Safety-sensitive functions shall include:

1.3.51.1 All time at an employer or shipper plant, terminal, facility, or other property, or on any public property, waiting to be dispatched, unless the driver has been relieved from duty by the employer;

1.3.51.2 All time inspecting equipment as required by § 392.7 and §392.8 or otherwise inspecting, servicing, or conditioning any commercial motor vehicle at any time;

1.3.51.3 All time spent at the driving controls of a commercial motor vehicle in operation;

1.3.51.4 All time, other than driving time, in or upon any commercial motor vehicle except time spent resting in a sleeper berth (a berth conforming to the requirements of §393.76);

1.3.51.5 All time loading or unloading a vehicle, supervising, or assisting in the loading or unloading, attending a vehicle being loaded or unloaded, remaining in readiness to operate the vehicle, or in giving or receiving receipts for shipments loaded or unloaded; and

1.3.51.6. All time repairing, obtaining assistance, or remaining in attendance upon a disabled vehicle.

1.3.52 Screening Test (Also Known As Initial Test)

1.3.52.1 In drug testing, a test to eliminate "negative" urine specimens from further analysis or to identify a specimen that requires additional testing for the presence of drugs.

1.3.52.2 In alcohol testing, an analytical procedure to determine whether an employee may have a prohibited concentration of alcohol in a breath or saliva specimen.

1.3.53 Screening Test Technician (STT)

A person who instructs and assists employees in the alcohol testing process and operates an ASD.

1.3.54 Secretary

The Secretary of Transportation or the Secretary's designee.

1.3.55 Service Agent

Any person or entity, other than an employee of the employer, who provides services specified under 49 CFR Part 40 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 Part 40. Service agents are not employers for purposes of 49 CFR Part 40.

1.3.56 Shipping Container

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

1.3.57 Specimen Bottle

The bottle that, after being sealed and labeled according to the procedures in 49 CFR Part 40, is used to hold the urine specimen during transportation to the laboratory.

1.3.58 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.

1.3.59 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.

1.3.60 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.

1.3.61 Substituted Specimen

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

1.3.62 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.

1.3.63 Violation Rate

The number of drivers (as reported under Section 3.3.) found during random tests given under this part to have an alcohol concentration of 0.04 or greater, plus the number of drivers who refuse a random test required by this part, divided by the total reported number of drivers in the industry given random alcohol tests under this part plus the total reported number of drivers in the industry who refuse a random test required by this part.

1.4 Administrative Provisions

1.4.1 Application. (§40.1)

Part 40 tells all parties who conduct drug and alcohol tests required by Department of Transportation (DOT) agency regulations how to conduct these tests and what procedures to use. 49 CFR 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. Nothing in 49 CFR Part 40 is intended to supersede or conflict with the implementation of the Federal Railroad Administration's post-accident testing program (see 49 CFR 219.200).

1.4.2 Interpretations of 49 CFR Part 40. (§40.5)

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 49 CFR Part 40. DOT agencies may incorporate ODAPC/OGC interpretations in written guidance they issue concerning drug and alcohol testing matters. Only Part 40 interpretations issued after August 1, 2001, are considered valid.

1.4.3 Exemptions. (§40.7)

1.4.3.1 Exemption from any provision of 49 CFR Part 40, must be requested in writing from the Office of the Secretary of Transportation, under the provisions and standards of 49 CFR Part 5. Requests for an

exemption must be sent to the following address:

Department of Transportation
Deputy Assistant General Counsel for Regulation and Enforcement
400 7th Street, SW., Room 10424
Washington, DC 20590

1.4.3.2 Under the standards of 49 CFR Part 5, the Secretary will grant the request only if the request documents special or exceptional circumstances, not likely to be generally applicable and not contemplated in connection with the rulemaking that established 49 CFR Part 40, that make compliance with a specific provision of 49 CFR Part 40 impracticable.

1.4.3.3 If the DOT grants an exemption, the applicant must agree to take steps specified to comply with the intent of the provision from which an exemption is granted.

1.4.3.4 The DOT will issue written responses to all exemption requests.

2. Employer Responsibilities.

2.1 Responsibilities of the Emp1oyer. (§40.11)

2.1.1 Employer Responsible for All Aspects of the Program.

The Employer is responsible for meeting all applicable requirements and procedures of 49 CFR Part 40. The Employer is responsible for all actions of its officials, representatives, and agents (including service agents) in carrying out the requirements of the DOT agency regulations.

2.1.2 Compliance With Part 40 - a Term of All Contracts.

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.

2.2 Employer Authority Not Affected. (§382.111)

Except as expressly provided in 49 CFR Part 382, nothing in Part 382 shall be construed to affect the authority of employers, or the rights of drivers, with respect to the use of alcohol, or the use of controlled substances, including authority and rights with respect to testing and rehabilitation.

2.3 Employer Policy on the Misuse of Alcohol and Use of Controlled Substances. (§382.601)

2.3.1 Materials to be Provided.

The Employer shall provide educational materials that explain the requirements of 49 CFR Part 382 and the Employer's policies and procedures with respect to meeting these requirements.

2.3.1.1 The Employer shall ensure that a copy of these materials is distributed to each driver prior to the start of alcohol and controlled substances testing under this part and to each driver subsequently hired or transferred into a position requiring driving a commercial motor vehicle.

2.3.1.2 The Employer shall provide written notice to representatives of employee organizations of the availability of this information.

2.3.2 Matter to be Included in Materials.

The materials to be made available to drivers shall include detailed discussion of at least the following:

2.3.2.1 The identity of the person designated by the Employer to answer driver questions about the materials;

2.3.2.2 The categories of drivers who are subject to the provisions of this part;

2.3.2.3 Sufficient information about the safety-sensitive functions performed by those drivers to make clear what period of the work day the driver is required to be in compliance with this part;

2.3.2.4 Specific information concerning driver conduct that is prohibited by this part;

2.3.2.5 The circumstances under which a driver will be tested for alcohol and/or controlled substances under this part, including post-accident testing under Section 3.2;

2.3.2.6 The procedures that will be used to test for the presence of alcohol and controlled substances, protect the driver and the integrity of the testing processes, safeguard the validity of the test results, and ensure that those results are attributed to the correct driver, including post-accident information, procedures and instructions required by paragraph 3.2.5;

2.3.2.7 The requirement that a driver submit to alcohol and controlled substances tests administered in accordance with this part;

2.3.2.8 An explanation of what constitutes a refusal to submit to an alcohol or controlled substances test and the attendant consequences;

2.3.2.9 The consequences for drivers found to have violated Section 2.8, including the requirement that the driver be removed immediately from safety-sensitive functions, and the procedures under Section 16.13;

2.3.2.10 The consequences for drivers found to have an alcohol concentration of 0.02 or greater but less than 0.04;

2.3.2.11 Information concerning the effects of alcohol and controlled substances use on an individual's health, work, and personal life; signs and symptoms of an alcohol or a controlled substances problem (the driver's or a co-worker(s); and available methods of intervening when an alcohol or a controlled substances problem is suspected, including confrontation, referral to any employee assistance program and/or referral to

management.

2.3.3 Additional Employer Policies.

The materials supplied to drivers may also include information on additional Employer policies with respect to the use of alcohol or controlled substances, including any consequences for a driver found to have a specified alcohol or controlled substances level, that are based on the Employer's authority independent of 49 CFR Part 382. Any such additional policies or consequences must be clearly and obviously described as being based on independent authority. This Employer's additional policies are listed on Exhibit A to this policy.

2.3.4 Driver to Acknowledge Receipt of Materials.

Each driver is required to sign a statement certifying that he or she has received a copy of these materials described in this section. The Employer shall maintain the original of the signed certificate and may provide a copy of the certificate to the driver.

2.4 Training for Supervisors. (§382.603)

The employer shall ensure that all persons designated to supervise drivers receive at least 60 minutes of training on alcohol misuse and receive at least an additional 60 minutes of training on controlled substances use. The training will be used by the supervisors to determine whether reasonable suspicion exists to require a driver to undergo testing under section 3.4. The training shall include the physical, behavioral, speech, and performance indicators of probable alcohol misuse and use of controlled substances.

2.5 Responsibilities of Certain Employees.

2.5.1 Designated Employer Representative(s) (DER).

The DER is responsible for providing oversight, evaluation and interpretation of this plan; providing guidance and counseling; reviewing all discipline applied under this Plan for consistency and conformance to federal policies and procedures; scheduling random drug and alcohol testing; and, maintaining a locked file system (separate from personnel records) on drug and alcohol testing results.

2.5.2 Supervisor(s).

Supervisors are responsible for observing the performance and behavior of drivers. The supervisor must document observations suggestive of the need for reasonable suspicion and post-accident testing of a driver.

2.5.3 Notifications to Driver(s). (§382.l13)

Before performing an alcohol or controlled substances test under part 382, each employer shall notify a driver that the alcohol or controlled substances test is required by Part 382. No employer shall falsely represent that a test is administered under Part 382.

2.6 DOT and Non-DOT Tests. (§40.13)

2.6.1 DOT Tests Separate.

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

2.6.2 DOT Tests Take Priority.

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

2.6.3 Limitation on Tests on DOT Specimens.

Except as provided in paragraph 2.6.4, no tests may be performed on DOT urine or breath specimens other than those specifically authorized by 49 CFR Part 40 or DOT agency regulations. For example, a DOT urine specimen may not be tested 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.

2.6.4 Exception to Limitation on Tests on DOT Specimens.

The single exception to paragraph 2.6.3 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.

2.6.5 DOT Test Results May Not Be Disregarded.

No one is permitted to change or disregard the results of DOT tests based on the results of non-DOT tests. For example, a verified positive DOT drug test result may not be disregarded because the employee presents a negative test result from a blood or urine specimen collected by the employee's physician or because a DNA test result purports to question the identity of the DOT specimen.

2.6.6 Custody and Control Form (CCF) and Alcohol Testing Form (ATF) May Only Be Used for DOT Testing.

The CCF or the ATF may not be used in 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 CCF and ATF must be used for all DOT-mandated drug and alcohol tests.

2.7 Use of Service Agents to Meet DOT Drug and Alcohol Testing Requirements. (§40.l5) (§40.17)

2.7.1 Employer Responsible Despite Use of Service Agents.

Although the Employer 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 Subpart Q and other applicable provisions of 49 CFR Part 40, this Employer is responsible for ensuring that the service agents it uses meet the qualifications set forth in 49 CFR Part 40 (e.g., Section 8.1 for MROs). This Employer may require service agents to show it documentation that they meet the requirements of 49 CFR Part 40 (e.g., documentation of MRO qualifications required by paragraph 8.1.6. Further, this Employer remains responsible for compliance with all applicable requirements of 49 CFR Part 40 and other DOT drug and alcohol testing regulations, even when a service agent is used. This Employer acknowledges that if it violates 49 CFR Part 40 or other DOT drug and alcohol testing regulations because a service agent has not provided services as DOT rules require, a DOT agency can subject this Employer to sanctions. This Employer is aware that good faith use of a service agent is not a defense in an enforcement action initiated by a DOT agency in which this Employer'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.

2.7.1.1 A service agent may not act as this Employer's DER.

2.7.1.2 This Employer acknowledges that it is responsible for obtaining information required by 49 CFR Part 40 from its service agents, whether or not this Employer chooses to use a C/TPA as an intermediary in transmitting information to it. For example, suppose an applicant for a

safety-sensitive job takes a pre-employment drug test, but there is a significant delay in this Employer's receipt of the test result from an MRO or C/TPA. This Employer must not assume that "no news is good news" and permit the applicant to perform safety-sensitive duties before receiving the result. This is a violation of the Department's regulations.

2.7.2 Employer May Not Stand Down Employees. (§40.21)

This Employer acknowledges that it may not stand employees down, except consistent with a waiver a DOT agency grants under this section. This Employer does not now have a waiver. A waiver can be obtained from the concerned DOT agency pursuant to the regulations set forth at 49 CFR Part 40 Section §40.21(b) and §382.119.

2.8 Prohibitions on Alcohol and Controlled Substance Use While on Duty.

2.8.1 Alcohol Impaired Drivers Shall Not Work. (§382.201)

No driver shall report for duty or remain on duty requiring the performance of safety-sensitive functions while having an alcohol concentration of 0.04 or greater. No employer having actual knowledge that a driver has an alcohol concentration of 0.04 or greater shall permit the driver to perform or continue to perform safety-sensitive functions.

2.8.2 No Drinking on Duty. (§382.205)

No driver shall use alcohol while performing safety-sensitive functions. No employer having actual knowledge that a driver is using alcohol while performing safety-sensitive functions shall permit the driver to perform or continue to perform safety-sensitive functions.

2.8.3 No Driving Within 4 Hours after Drinking. (§382.207)

No driver shall perform safety-sensitive functions within four hours after using alcohol. No employer having actual knowledge that a driver has used alcohol within four hours shall permit a driver to perform or continue to perform safety-sensitive functions.

2.8.4 No Drinking after an Accident. (§382.209)

No driver required to take a post-accident alcohol test under Section 3.2 of this part shall use alcohol for eight hours following the accident, or until he/she undergoes a post-accident alcohol test, whichever occurs first.

2.8.5 No Driver Shall Refuse to Test. (§382.2l1)

No driver shall refuse to submit to a post-accident alcohol or controlled substances test required under Section 3.2, a random alcohol or controlled substances test required under Section 3.3, a reasonable suspicion alcohol or controlled substances test required under Section 3.4, or a follow-up alcohol or controlled substances test required under Section 3.5. No employer shall permit a driver who refuses to submit to such tests to perform or continue to perform safety-sensitive functions.

2.8.6 No Driving While Using a Controlled Substance. (§ 382.2l3)

2.8.6.1 No driver shall report for duty or remain on duty requiring the performance of safety-sensitive functions when the driver uses any controlled substance, except when the use is pursuant to the instructions of a licensed medical practitioner, as defined in paragraph 1.3.41, who has advised the driver that the substance will not adversely affect the driver's ability to safely operate a commercial motor vehicle.

2.8.6.2 No employer having actual knowledge that a driver has used a

controlled substance shall permit the driver to perform or continue to perform a safety-sensitive function.

2.8.6.3 An employer may require a driver to inform the employer of any therapeutic drug use.

2.8.7 No Driver Who Tests Positive Shall Work. (§382.2l5)

No driver shall report for duty, remain on duty or perform a safety-sensitive function, if the driver tests positive or has adulterated or substituted a test specimen for controlled substances. No employer having actual knowledge that a driver has tested positive or has adulterated or substituted a test specimen for controlled substances shall permit the driver to perform or continue to perform safety-sensitive functions.

2.8.8 Requirement for Driver Reinstatement. (§382.503)

No driver who has engaged in conduct prohibited by Section 2.8 shall perform safety-sensitive functions, including driving a commercial motor vehicle, unless the driver has met the requirements of Section 2.13. No employer shall permit a driver who has engaged in conduct prohibited by Section 2.8 to perform safety-sensitive functions, including driving a commercial motor vehicle, unless the driver has met the requirements of Section 16.13.

2.9 Removal from Safety-Sensitive Function. (§382.501)

2.9.1 No Driving Impaired.

Except as provided in Sections 16.3, 16.4 and 16.13, no driver shall perform safety-sensitive functions, including driving a commercial motor vehicle, if the driver has engaged in conduct prohibited by Section 2.8 or an alcohol or controlled substances rule of another DOT agency.

2.9.2 Employer Shall Not Permit an Impaired Driver to Perform Safety-Sensitive Functions.

No employer shall permit any driver to perform safety-sensitive functions, including driving a commercial motor vehicle, if the employer has determined that the driver has violated this section.

2.9.3 Motor Vehicle Defined.

"Commercial motor vehicle" means a commercial motor vehicle in commerce as defined in paragraph 1.3.19, and a commercial motor vehicle in interstate commerce as defined in 49 CFR Part 390.

2.10 Employee Admission of Alcohol and Controlled Substances Use. (§382.121)

2.10.1 Employees Who Admit Drug or Alcohol Misuse Not Subject to Parts 40 and 382.

Employees who admit to alcohol misuse or controlled substances use are not subject to the referral, evaluation and treatment requirements of Part 382 and Part 40, provided that:

2.10.1.1 The admission is in accordance with a written employer-established voluntary self-identification program or policy that meets the requirements of paragraph 2.10.2;

2.10.1.2 The driver does not self-identify in order to avoid testing under the requirements of this part;

2.10.1.3 The driver makes the admission of alcohol misuse or controlled substances use prior to performing a safety sensitive function (i.e., prior to reporting for duty); and

2.10.1.4 The driver does not perform a safety sensitive function until the employer is satisfied that the employee has been evaluated and has successfully completed education or treatment requirements in accordance with the self-identification program guidelines.

2.10.2 Elements of a Qualified Self-identification Program.

A qualified voluntary self-identification program or policy must contain the following elements:

2.10.2.1 It must prohibit the employer from taking adverse action against an employee making a voluntary admission of alcohol misuse or controlled substances use within the parameters of the program or policy and paragraph 2.10.1;

2.10.2.2 It must allow the employee sufficient opportunity to seek evaluation, education or treatment to establish control over the employee's drug or alcohol problem;

2.10.2.3 It must permit the employee to return to safety-sensitive duties only upon successful completion of an educational or treatment program, as determined by a drug and alcohol abuse evaluation expert, i.e., employee assistance professional, substance abuse professional, or qualified drug and alcohol counselor;

2.10.2.4 It must ensure that:

2.10.2.4.1 Prior to the employee participating in a safety-sensitive function, the employee shall undergo a return to duty test with a result indicating an alcohol concentration of less than 0.02; and/or

2.10.2.4.2 Prior to the employee participating in a safety-sensitive function, the employee shall undergo a return to duty controlled substance test with a verified negative test result for controlled substances use; and

2.10.2.5 It may incorporate employee monitoring and include non-DOT follow-up testing.

2.11 Other Alcohol-Related Conduct. (§382.505)

2.11.1 Alcohol Concentration Between .02 and .04.

No driver tested under the provisions of Part 382 who is found to have an alcohol concentration of 0.02 or greater but less than 0.04 shall perform or continue to

perform safety-sensitive functions for an employer, including driving a commercial motor vehicle, nor shall an employer permit the driver to perform or continue to perform safety-sensitive functions, until the start of the driver's next regularly scheduled duty period, but not less than 24 hours following administration of the test.

2.11.2 No Employer Action for Concentration Below .02.

Except as provided in paragraph 2.11.1, no employer shall take any action under this part against a driver based solely on test results showing an alcohol concentration less than 0.04. This does not prohibit an employer with authority independent of this part from taking any action otherwise consistent with law.

2.12 Penalties. (§382.507)

Any employer or driver who violates the requirements of 49 CFR Part 40 or Part 382 shall be subject to the civil and/or criminal penalty provisions of 49 U.S.C. 521(b).

3. Alcohol and Drug Testing Required.

3.1 Pre-Employment Testing. (§382.30l)

3.1.1 Alcohol and Controlled Substances Testing.

Prior to the first time a driver performs safety-sensitive functions for an employer, the driver shall undergo testing for controlled substances as a condition prior to being used, unless the employer uses the exception in paragraph 3.1.2. The Employer shall not allow a driver, who the Employer intends to hire or use, to perform safety-sensitive functions unless the driver has received a controlled substances test result from the MRO or C/TPA indicating a verified negative test result for the driver.

3.1.2 Exception for Pre-Employment Controlled Substances Testing.

An employer is not required to administer a controlled substances test required by paragraph 3.1.1 if:

3.1.2.1 The driver has participated in a controlled substances testing program that meets the requirements of this part within the previous 30 days; and

3.1.2.2 While participating in that program, either

3.1.2.2.1 Was tested for controlled substances within the past 6 months (from the date of application with the employer); or

3.1.2.2.2 Participated in the random controlled substances testing program for the previous 12 months (from the date of application with the employer); and

3.1.2.3 The Employer ensures that no prior employer of the driver of whom the employer has knowledge has records of a violation of this part or the controlled substances use rule of another DOT agency within the previous six months.

3.1.3 Information to Be Obtained.

3.1.3.1 If the Employer exercises the exception in paragraph 3.1.2, the Employer or C/TPA shall contact the controlled substances testing program(s) in which the driver participates or participated and shall obtain and retain from the testing program(s) the following information:

3.1.3.1.1 Name(s) and address(es) of the program(s).

3.1.3.1.2 Verification that the driver participates or participated in the program(s).

3.1.3.1.3 Verification that the program(s) conforms to 49 CFR Part 40.

3.1.3.1.4 Verification that the driver is qualified under the rules of Part 382, including that the driver has not refused to be tested for controlled substances.

3.1.3.1.5 The date the driver was last tested for controlled substances.

3.1.3.1.6 The results of any tests taken within the previous six months and any other violations of Section 2.8.

3.1.4 Occasional Drivers.

If the Employer uses, but does not employ, a driver more than once a year to operate commercial motor vehicles, the Employer must obtain the information in paragraph 3.1.3.1 at least once every six months. The records prepared under this paragraph shall be maintained in accordance with Section 18.9. If the Employer cannot verify that the driver is participating in a controlled substances testing program in accordance with this part and Part 40, the Employer shall conduct a pre-employment alcohol and/or controlled substances test.

3.1.5 Permitted Pre-Employment Alcohol Testing.

The employer may, but is not required to, conduct pre-employment alcohol testing under this part. If the employer chooses to conduct pre-employment alcohol testing, it must comply with the following requirements:

3.1.5.1 It must conduct a pre-employment alcohol test before the first performance of safety-sensitive functions by every covered employee (whether a new employee or someone who has transferred to a position involving the performance of safety-sensitive functions).

3.1.5.2 It must treat all safety-sensitive employees performing safety-sensitive functions the same for the purpose of pre-employment alcohol testing (i.e., it must not test some covered employees and not others).

3.1.5.3 It must conduct the pre-employment tests after making a contingent offer of employment or transfer, subject to the employee passing the pre-employment alcohol test.

3.1.5.4 It must conduct all pre-employment alcohol tests using the alcohol testing procedures

3.1.5.5 It must not allow a covered employee to begin performing safety-sensitive functions unless the result of the employee's test indicates an alcohol concentration of less than 0.04.

3.2 Post-Accident Testing. (§382.303)

3.2.1 Testing Required.

As soon as practicable following an occurrence involving a commercial motor vehicle operating on a public road in commerce, the Employer shall test for alcohol and controlled substances each surviving driver:

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

3.2.1.2 Who receives a citation within 8 hours of the occurrence under State or local law for a moving traffic violation arising from the accident shall be tested for alcohol and drugs; if the driver receives a citation within 32 hours of the occurrence under State or local law for a moving traffic violation arising from the accident shall be tested for controlled substances only, if the accident involved:

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

3.2.1.2.2 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.

3.2.1.3 This table notes when a post-accident test is required to be conducted by paragraph 3.2.1.

Type of accident involved	Citation issued to the CMV driver			Test must be performed by employer
Human fatality	+	YES	=	YES
Human fatality	+	NO	=	YES
Bodily injury with immediate medical treatment away from the scene	+	YES	=	YES
Bodily injury with immediate medical treatment away from the scene	+	NO	=	NO
Disabling damage to any motor vehicle requiring tow away	+	YES	=	YES
Disabling damage to any motor vehicle requiring tow away	+	NO	=	NO

3.2.2 Alcohol Tests.

If a test required by this section is not administered within two hours following the accident, the Employer shall prepare and maintain on file a record stating the reasons the test was not promptly administered. If a test required by this section is not administered within eight hours following the accident, the Employer shall cease attempts to administer an alcohol test and shall prepare and maintain the same record. Records shall be submitted to the FMCSA upon request.

3.2.3 Controlled Substance Tests.

If a test required by this section is not administered within 32 hours following the accident, the employer shall cease attempts to administer a controlled substances test, and prepare and maintain on file a record stating the reasons the test was not promptly administered. Records shall be submitted to the FMCSA upon request.

3.2.4 Driver Must Remain Available for Post Accident Test.

A driver who is subject to post-accident testing shall remain readily available for such testing or may be deemed by the employer to have refused to submit to testing. Nothing in this section shall be construed to require the delay of necessary medical attention for injured people following an accident or to prohibit a driver from leaving the scene of an accident for the period necessary to obtain assistance in responding to the accident, or to obtain necessary emergency medical care.

3.2.5 Employer Shall Provide Driver with Post Accident Procedures.

The Employer shall provide drivers with necessary post-accident information, procedures and instructions, prior to the driver operating a commercial motor vehicle, so that drivers will be able to comply with the requirements of this section.

3.2.6 Tests Meeting the Requirements of this Section.

3.2.6.1 The results of a breath or blood test for the use of alcohol, conducted by Federal, State, or local officials having independent authority for the test, shall be considered to meet the requirements of this section, provided such tests conform to the applicable Federal, State or local alcohol testing requirements, and that the results of the tests are obtained by the employer.

3.2.6.2 The results of a urine test for the use of controlled substances, conducted by Federal, State, or local officials having independent authority for the test, shall be considered to meet the requirements of this section, provided such tests conform to the applicable Federal, State or local controlled substances testing requirements, and that the results of the tests are obtained by the employer.

3.2.7 Exception.

Section 3.2. does not apply to:

3.2.7.1 An occurrence involving only boarding or alighting from a stationary motor vehicle; or

3.2.7.2 An occurrence involving only the loading or unloading of cargo; or

3.2.7.3 An occurrence in the course of the operation of a passenger car or a multipurpose passenger vehicle (as defined in 49 CFR Part 571.3) by an employer unless the motor vehicle is transporting passengers for hire or hazardous materials of a type and quantity that require the motor vehicle to be marked or placarded in accordance with 49 CFR Part 177.823.

3.3 Random Testing. (§382.305)

3.3.1 All Drivers Required to Test.

The Employer shall comply with the provisions of this Section. Every driver shall submit to random alcohol and controlled substance testing as required in this Section.

3.3.2 Minimum Testing Rates.

3.3.2.1 Except as provided in paragraphs 3.3.3 through 3.3.5, the minimum annual percentage rate for random alcohol testing shall be 10 percent of the average number of driver positions.

3.3.2.2 Except as provided in paragraphs 3.3.6 through 3.3.8, the minimum annual percentage rate for random controlled substances testing shall be 50 percent of the average number of driver positions.

3.3.3 Adjustment in Testing Rate.

The FMCSA Administrator's decision to increase or decrease the minimum annual percentage rate for alcohol testing is based on the reported violation rate for the entire industry. All information used for this determination is drawn from the alcohol management information system reports required by Section 18.10. In order to ensure reliability of the data, the FMCSA Administrator considers the quality and completeness of the reported data, may obtain additional information or reports from employers, and may make appropriate modifications in calculating the industry

violation rate. In the event of a change in the annual percentage rate, the FMCSA Administrator will publish in the Federal Register the minimum annual percentage rate for random alcohol testing of drivers. The new minimum annual percentage rate for random alcohol testing will be applicable starting January 1 of the calendar year following publication in the Federal Register.

3.3.4 Permitted FMCSA Adjustments.

3.3.4.1 When the minimum annual percentage rate for random alcohol testing is 25 percent or more, the FMCSA Administrator may lower this rate to 10 percent of all driver positions if the FMCSA Administrator determines that the data received under the reporting requirements of Section 18.10 for two consecutive calendar years indicate that the violation rate is less than 0.5 percent.

3.3.4.2 When the minimum annual percentage rate for random alcohol testing is 50 percent, the FMCSA Administrator may lower this rate to 25 percent of all driver positions if the FMCSA Administrator determines that the data received under the reporting requirements of Section 18.10 for two consecutive calendar years indicate that the violation rate is less than 1.0 percent but equal to or greater than 0.5 percent.

3.3.5 Increases in Testing Rate.

3.3.5.1 When the minimum annual percentage rate for random alcohol testing is 10 percent, and the data received under the reporting requirements of Section 18.10 for that calendar year indicate that the violation rate is equal to or greater than 0.5 percent, but less than 1.0 percent, the FMCSA Administrator will increase the minimum annual percentage rate for random alcohol testing to 25 percent for all driver positions.

3.3.5.2 When the minimum annual percentage rate for random alcohol testing is 25 percent or less, and the data received under the reporting requirements of Section 18.10 for that calendar year indicate that the violation rate is equal to or greater than 1.0 percent, the FMCSA Administrator will increase the minimum annual percentage rate for random alcohol testing to 50 percent for all driver positions.

3.3.6 Basis for Administrator's Decision.

The FMCSA Administrator's decision to increase or decrease the minimum annual percentage rate for controlled substances testing is based on the reported positive rate for the entire industry. All information used for this determination is drawn from the controlled substances management information system reports required by Section 18.10 of this part. In order to ensure reliability of the data, the FMCSA Administrator considers the quality and completeness of the reported data, may obtain additional information or reports from employers, and may make appropriate modifications in calculating the industry positive rate. In the event of a change in the annual percentage rate, the FMCSA Administrator will publish in the Federal Register the minimum annual percentage rate for random controlled substances testing of drivers. The new minimum annual percentage rate for random controlled substances testing will be applicable starting January 1 of the calendar year following publication in the Federal Register.

3.3.7 Administrator's Discretion.

When the minimum annual percentage rate for random controlled substances testing is 50 percent, the FMCSA Administrator may lower this rate to 25 percent of all driver positions if the FMCSA Administrator determines that the data received under the reporting requirements of Section 18.10 for two consecutive calendar years indicate that the positive rate is less than 1.0 percent.

3.3.8 Required Rate Increase.

When the minimum annual percentage rate for random controlled substances testing is 25 percent, and the data received under the reporting requirements of Section 18.10 for any calendar year indicate that the reported positive rate is equal to or greater than 1.0 percent, the FMCSA Administrator will increase the minimum annual percentage rate for random controlled substances testing to 50 percent of all driver positions.

3.3.9 Selection Methods.

The selection of drivers for random alcohol and controlled substances testing shall be made by a scientifically valid method, such as a random number table or a computer-based random number generator that is matched with drivers' Social Security numbers, payroll identification numbers, or other comparable identifying numbers. Under the selection process used, each driver shall have an equal chance of being tested each time selections are made. Each driver selected for testing shall be tested during the selection period.

3.3.10 Number of Drivers to Be Tested.

The Employer shall randomly select a sufficient number of drivers for testing during each calendar year to equal an annual rate not less than the minimum annual percentage rate for random alcohol and controlled substances testing determined by the FMCSA Administrator. If the Employer conducts random testing for alcohol and/or controlled substances through a C/TPA, the number of drivers to be tested may be calculated for each individual employer or may be based on the total number of drivers covered by the C/TPA who are subject to random alcohol and/or controlled substances testing at the same minimum annual percentage rate under this part.

3.3.11 Tests Unannounced.

The Employer shall ensure that random alcohol and controlled substances tests are unannounced and that the dates for administering random alcohol and controlled substances tests are spread reasonably throughout the calendar year.

3.3.12 Random Tests to Be Conducted Immediately.

The Employer requires that each driver who is notified of selection for random alcohol and/or controlled substances testing proceeds to the test site immediately; provided, however, if the driver is performing a safety-sensitive function, other than driving a commercial motor vehicle, at the time of notification, the employer shall instead ensure that the driver ceases to perform the safety-sensitive function and proceeds to the testing site as soon as possible.

3.3.13 Time for Testing for Alcohol.

A driver shall only be tested for alcohol while the driver is performing safety-sensitive functions, just before the driver is to perform safety-sensitive functions, or just after the driver has ceased performing such functions.

3.3.14 Random Testing for More than One Agency.

If a given driver is subject to random alcohol or controlled substances testing under

the random alcohol or controlled substances testing rules of more than one DOT agency for the Employer, the driver shall be subject to random alcohol and/or controlled substances testing at the annual percentage rate established for the calendar year by the DOT agency regulating more than 50 percent of the driver's function.

3.3.15 Rules When More than One Agency is Testing.

If the Employer is required to conduct random alcohol or controlled substances testing under the alcohol or controlled substances testing rules of more than one DOT agency, the Employer may:

3.3.15.1 Establish separate pools for random selection, with each pool containing the DOT-covered employees who are subject to testing at the same required minimum annual percentage rate; or

3.3.15.2 Randomly select such employees for testing at the highest minimum annual percentage rate established for the calendar year by any DOT agency to which the employer is subject.

3.4 Reasonable Suspicion Testing. (§382.307)

3.4.1 Basis for Reasonable Suspicion Testing for Alcohol.

The Employer requires a driver to submit to an alcohol test when the Employer has reasonable suspicion to believe that the driver has violated the prohibitions of Section 2.8 concerning alcohol. The employer's determination that reasonable suspicion exists to require the driver to undergo an alcohol test must be based on specific, contemporaneous, articulable observations concerning the appearance, behavior, speech or body odors of the driver.

3.4.2 Basis for Reasonable Suspicion Testing for Controlled Substances.

The Employer shall require a driver to submit to a controlled substances test when the Employer has reasonable suspicion to believe that the driver has violated the prohibitions of Section 2.8 concerning controlled substances. The Employer's determination that reasonable suspicion exists to require the driver to undergo a controlled substances test must be based on specific, contemporaneous, articulable observations concerning the appearance, behavior, speech or body odors of the driver. The observations may include indications of the chronic and/or withdrawal effects of controlled substances.

3.4.3 Who Makes the Observation for Reasonable Suspicion Testing.

The required observations for alcohol and/or controlled substances reasonable suspicion testing shall be made by a supervisor or Employer official who is trained in accordance with Section 2.4. The person who makes the determination that reasonable suspicion exists shall not conduct the alcohol test of the driver.

3.4.4 When Observations for Alcohol Testing Must Be Made.

Alcohol testing is authorized by this section only if the observations required by paragraph 3.4.1 are made during, just preceding, or just after the period of the work day that the driver is required to be in compliance with this part. A driver may be directed by the Employer to only undergo reasonable suspicion testing while the driver is performing safety-sensitive functions, just before the driver is to perform safety-sensitive functions, or just after the driver has ceased performing such functions.

3.4.5 Alcohol Testing Not Timely Made.

3.4.5.1 If an alcohol test required by this section is not administered

within two hours following the determination under paragraph 3.4.1, the Employer shall prepare and maintain on file a record stating the reasons the alcohol test was not promptly administered. If an alcohol test required by this section is not administered within eight hours following the determination under paragraph 3.4.1, the Employer shall cease attempts to administer an alcohol test and shall state in the record the reasons for not administering the test.

3.4.5.2 Notwithstanding the absence of a reasonable suspicion alcohol test under this section, no driver shall report for duty or remain on duty requiring the performance of safety-sensitive functions while the driver is under the influence of or impaired by alcohol, as shown by the behavior, speech, and performance indicators of alcohol misuse, nor shall an employer permit the driver to perform or continue to perform safety-sensitive functions, until:

3.4.5.2.1 An alcohol test is administered and the driver's alcohol concentration measures less than 0.02; or

3.4.5.2.2 Twenty-four hours have elapsed following the determination under paragraph 3.4.1 that there is reasonable suspicion to believe that the driver has violated the prohibitions in this part concerning the use of alcohol.

3.4.5.3 Except as provided in paragraph 3.4.5.2, the Employer shall take no action under this part against a driver based solely on the driver's behavior and appearance, with respect to alcohol use, in the absence of an alcohol test. This does not prohibit an employer with independent authority of this part from taking any action otherwise consistent with law.

3.4.6 Records Required.

A written record shall be made of the observations leading to an alcohol or controlled substance reasonable suspicion test, and signed by the supervisor or official of the Employer who made the observations, within 24 hours of the observed behavior or before the results of the controlled substances test are released, whichever is earlier.

3.5 Return-to-Duty Testing. (§382.309)

The requirements for return-to-duty testing must be performed in accordance with Section 16.13.

3.6 Follow-up Testing. (§382.3l1)

Follow-up testing must be performed in accordance with Section 16.14.

3.7 Actions after Receiving Verified Test Results. (§40.23)

3.7.1 Employer Action upon Receiving Verified Positive Result.

Upon receipt of an initial verified positive drug test result, the Employer shall immediately remove the employee involved from performing safety-sensitive functions. Removal of an employee from performing safety-sensitive functions shall not be delayed until this Employer receives the written report or the result of a split specimen test.

3.7.2 Employer Action upon Receiving Verified Adulterated or Substituted Result.

Upon receipt of an initial verified adulterated or substituted drug test result, the Employer shall consider this a refusal to test and immediately remove the employee involved from performing safety-sensitive functions. Removal of an employee from performing safety-sensitive functions shall not be delayed until this Employer receives the written report or the result of a split specimen test.

3.7.3 Employer Action upon Receiving .04 or Higher Alcohol Result.

Upon receipt of an alcohol test result of 0.04 or higher, this Employer shall immediately remove the employee involved from performing safety-sensitive functions. If this Employer receives an alcohol test result of 0.02 - 0.039, this Employer shall temporarily remove the employee involved from performing safety-sensitive functions, as provided in applicable DOT agency regulations. Removal of an employee from performing safety-sensitive functions shall not be delayed until this Employer receives the written report of the result of the test.

3.7.4 Employer Action upon Receiving Verified Positive, Adulterated or Substituted Result.

When an employee has a verified positive, adulterated, or substituted test result, or has otherwise violated a DOT agency drug and alcohol regulation, the Employer shall not return the employee to the performance of safety-sensitive functions until or unless the employee successfully completes the return-to-duty process of Section 16.13.

3.7.5 Employer Action upon Receiving Dilute Result.

If this Employer receives a drug test result indicating that the employee's specimen was dilute, this Employer will take action as provided in Section 10.4.

3.7.6 Employer Action upon Receiving Invalid Result.

If this Employer receives a drug test result indicating that the employee's specimen was invalid and that a second collection must take place under direct observation:

3.7.6.1 The employee shall be immediately directed to provide a new specimen under direct observation.

3.7.6.2 No consequences shall be attached to the finding that the test was invalid other than collecting a new specimen under direct observation.

3.7.6.3 No advance notice of this test requirement shall be given to the employee.

3.7.6.4 The collector shall be instructed to note on the CCF the same reason (e.g., random test, post-accident test) as for the original collection.

3.7.7 Employer Action upon Receiving Cancelled Result.

If this Employer receives a cancelled test result when a negative result is required (e.g., pre-employment, return-to-duty, or follow-up test), the employee shall be directed to provide another specimen immediately.

3.7.8 Additional Actions.

Additional actions required by DOT agency regulations are applicable to this Employer.

3.7.9 Test Results Must Not Be Altered.

Drug or alcohol test results transmitted to this Employer by an MRO, BAT, or C/TPA must not be altered.

3.8 Pre-employment Investigation of Employees Intended to Perform Safety-Sensitive Duties. (§40.25) (§382.413)

3.8.1 Information Shall Be Requested.

After obtaining an employee's written consent, this Employer shall request the information about the employee listed in paragraph 3.8.2. This requirement applies only to employees seeking to begin performing safety-sensitive duties for this Employer 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 employee shall not be permitted to perform safety-sensitive functions.

3.8.2 Information to Be Requested.

The information listed in this paragraph shall be requested from DOT-regulated employers who have employed the employee during any period during the three years before the date of the employee's application or transfer:

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

3.8.2.2 Verified positive drug tests;

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

3.8.2.4 Other violations of DOT agency drug and alcohol testing regulations; and

3.8.2.5 With respect to any employee who violated a DOT drug and alcohol regulation, documentation of the employee's successful completion of DOT return-to-duty requirements (including follow-up tests). If the previous employer does not have information about the return-to-duty process (e.g., an employer who terminated the employee following a positive test result), this employer must seek to obtain this information from the employee.

3.8.3 Information Includes Other Previous Employers.

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.

3.8.4 Information Should Be Obtained Before Employee Performs Safety-Sensitive Work.

If feasible, this information must be obtained and reviewed before the employee first performs safety-sensitive functions. If this is not feasible, the information must be obtained and reviewed as soon as possible. However, the employee shall not be permitted to perform safety-sensitive functions after 30 days from the date on which the employee first performed safety-sensitive functions, unless this Employer has obtained or made and documented a good faith effort to obtain this information.

3.8.5 If Information of Violation Discovered.

If this Employer obtains information that the employee has violated a DOT agency drug and alcohol regulation, the employee shall not be used to perform safety-

sensitive functions unless this Employer also obtains 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.

3.8.6 Written Consent of Employee to Be Provided.

Each of the employers from whom this Employer requests information under paragraph 3.8.2 shall be provided written consent for the release of the information cited in paragraph 3.8.2.

3.8.7 Release of Information Must Be in Writing.

The release of information under this section must be in any written form (e.g., fax, e-mail, letter) that ensures confidentiality. As the previous employer, this Employer shall 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.

3.8.8 Employer's Response to Requests for Information.

If information is requested of this Employer pursuant to paragraph 3.8.2, this Employer shall, after reviewing the employee's specific, written consent, immediately release the requested information to the employer making the inquiry.

3.8.9 Written Record of Requested Information.

When this Employer requests the information required under this section, it shall maintain a written, confidential record of the information obtained or of the good faith efforts made to obtain the information. This information must be retained for three years from the date of the employee's first performance of safety-sensitive duties for this Employer.

3.8.10 Inquiry of Employee.

This Employer must also ask the employee whether he or she has tested positive, or refused to test, on any pre-employment drug or alcohol test administered by an employer to which the employee applied for, but did not obtain, safety-sensitive transportation work covered by DOT agency drug and alcohol testing rules during the past three years. If the employee admits that he or she had a positive test or a refusal to test, the employee must not be permitted to perform safety-sensitive functions for the Employer, until and unless the employee documents successful completion of the return-to-duty process (see paragraphs 3.8.2.5 and 3.8.5).

3.9 Employer Notifications. (§382.411)

3.9.1 Notification to Driver.

The Employer shall notify a driver of the results of a pre-employment controlled substance test conducted under this part, if the driver requests such results within 60 calendar days of being notified of the disposition of the employment application. The Employer shall notify a driver of the results of random, reasonable suspicion and post-accident tests for controlled substances conducted under this part if the test results are verified positive. The Employer shall also inform the driver which controlled substance or substances were verified as positive.

3.9.2 Efforts to Contact Driver.

The DER shall make reasonable efforts to contact and request each driver who submitted a specimen under the Employer's program, regardless of the driver's employment status, to contact and discuss the results of the controlled substances test with a medical review officer who has been unable to contact the driver.

3.9.3 Report to MRO. The DER shall immediately notify the medical review officer that the driver has been notified to contact the medical review officer within 72 hours.

3.10 Starting Date for Testing Programs. (§382.115)

3.10.1 Domestic Employers. All domestic-domiciled employers must implement the requirements of this part on the date the employer begins commercial motor vehicle operations.

3.10.2 Foreign Employers. All foreign-domiciled employers must implement the requirements of this part on the date the employer begins commercial motor vehicle operations in the United States.

3.11 Use of Management Information System (MIS) Form (§ 40.26)

An employer, who is required to report MIS data to FMCSA, must use the form and instructions at Appendix H to Part 40. The MIS report must be submitted in accordance with rule requirements (e.g. dates for submission, selection of companies required to submit, and method of reporting) established by FMCSA.

3.12 Employer May Not Require a Release. (§ 40.27)

An employer may not require a driver 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).

3.13 Additional Information. (§40.29)

Additional information on employer responsibilities can be found in the following sections:

1.3-- definition.
4.3-- information about DERs that employers must provide collectors.
5.3-- modifying CCFs, Use of foreign-language CCFs.
5.4-- use of non-Federal forms for DOT tests or Federal CCFs for non-DOT tests.
6.4-- requirements for direct observation.
7.12-7.13--blind specimen requirements.
9.2-- responsibility to ensure test of split specimen.
10.2-- action in ”shy bladder” situations.
10.4--actions following report of a dilute specimen.
10.9--actions following a report of a cancelled drug test.
10.10--actions following and consequences of non-fatal flaws in drug tests.
11.3-- information about DERs that employers must provide BATs and STTs.
12.3-- modifying ATFs; use of foreign-language ATFs.
12.4-- use of non-DOT forms for DOT tests or DOT ATFs for non-DOT tests.
12.8.3-.4--responsibility to follow instructions for ASDs.
14.3.2-- receipt and storage of alcohol test information.
15.3.3-.5-- actions in “shy lung” situations.
15.4--cancellation of alcohol tests.
15.6-- actions in “correctable flaw” situations in alcohol tests.
15.7-- actions following cancelled tests in alcohol tests.
15.8-- actions in “non-fatal flaw” situations in alcohol tests.
16.4-.5 -- responsibilities concerning SAP services.
16.8-.9-- prohibition on seeking second SAP evaluation or changing SAP recommendation.
16.12-- responsibilities concerning aftercare recommendations.

16.1 3 -- responsibilities concerning return-to-duty decision.
16.15-- responsibilities concerning follow-up tests.
17.1-- general confidentiality requirement.
17.2-- release of confidential information in litigation.
17.5--other circumstances for the release of confidential information.
17.6-- record retention requirements.
18.3-- choice of who reports drug testing information to employers.

4. Urine Collection Personnel. (§40.31)

4.1 Collectors Meeting the Requirements of this Subpart Are the Only Persons Authorized to Collect Urine Specimens for DOT Drug Testing.

4.1.1 Training Requirements. A collector must meet training requirements of Section 4.2.

4.1.2 Supervisor May Not Be Collector. The 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 immediate supervisor is permitted to do so under DOT agency drug and alcohol regulations.

4.1.3 Limit on Lab Personnel Acting as Collector. Anyone working for a HHS-certified laboratory (e.g., as a technician or accessioner) who could link the employee with a urine specimen, drug testing result, or laboratory report must not act as the collector for the employee being tested.

4.2 Training Requirements to Be a Collector. (§40.33)

4.2.1 Basic Information. A collector must be knowledgeable about 49 CFR Part 40, the current "DOT Urine Specimen Collection Procedures Guidelines," and DOT agency regulations applicable to the employers 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 (Department of Transportation, 400 7th Street, S.W., Room 10403, Washington DC, 20590, 202-366-3784, or on the ODAPC web site (http://www.dot.gov/ost/dapc).

4.2.2 Qualification Training. A collector must receive qualification training meeting the requirements of this paragraph. Qualification training must provide instruction on the following subjects:

4.2.2.1 All steps necessary to complete a collection correctly and the proper completion and transmission of the Federal Drug Testing Custody and Control Form (CCF);

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

4.2.2.3 Fatal flaws, correctable flaws, and how to correct problems in collections; and

4.2.2.4 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;

4.2.3 Initial Proficiency Demonstration. Following completion of qualification training under paragraph 4.2.2, the collector must demonstrate proficiency in collections under 49 CFR Part 40 by completing five consecutive error-free mock collections.

4.2.3.1 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.

4.2.3.2 Another person must monitor and evaluate the collector's performance, in person or by a means that provides real-time observation and interaction between the instructor and trainee, and attest in writing that the mock collections are "error-free." This person must be an individual who has demonstrated necessary knowledge, skills, and abilities by:

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

4.2.3.2.2 Conducting collector training under 49 CFR Part 40 for a year; or

4.2.3.2.3 Successfully completing a "train the trainer" course.

4.2.4 Schedule for Qualification Training and Initial Proficiency Demonstration.

4.2.4.1 A person who became a collector before August 1, 2001, and who has already met the requirements of paragraphs 4.2.2 and 4.2.3, does not have to meet them again.

4.2.4.2 A person who became a collector before August 1, 2001, and who has yet to meet the requirements of paragraphs 4.2.2 and 4.2.3, must do so no later than January 31, 2003.

4.2.4.3 A person who become a collector on or after August 1, 2001, must meet the requirements of paragraphs 4.2.2 and 4.2.3 before the person begins to perform collector functions.

4.2.5 Refresher Training. No less frequently than every five years from the date on which a collector satisfactorily completed the requirements of paragraphs 4.2.2 and

4.2.3, the collector must complete refresher training that meets all the requirements of paragraphs 4.2.2 and 4.2.3.

4.2.6 Error Correction Training. If a collector makes a mistake in the collection process that causes a test to be cancelled (i.e., a fatal or uncorrected flaw), that collector must undergo error correction training. This training must occur within 30 days of the date the collector is notified of the error that led to the need for retraining.

4.2.6.1 Error correction training must be provided and the collector's proficiency documented in writing by a person who meets the requirements of paragraphs 4.2.3.2.

4.2.6.2 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.

4.2.6.3 As part of the error correction training, the collector must demonstrate proficiency in the collection procedures of 49 CFR Part 40 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 error(s) occurred. The person providing the training must monitor and evaluate the collector's performance and attest in writing that the mock collections were "error-free."

4.2.7 Documentation. Each collector must maintain documentation showing that he or she currently meets 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 the collector's services.

4.3 Information to Be Provided to Collectors. (§40.35)

This Employer shall 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.

4.4 Additional Information. (§40.37)

Additional information on the role and functions of collectors can be found in the following sections:

1.3.19- definition.
5.2- steps to prepare and secure collection sites
5.3-5.4- use of CCF.
5.5-56- use of collection kit and shipping materials.
6.1-6.2- preliminary steps in collections.
6.3- role in checking specimens.
6.4- role in directly observed collections.
6.5- role in monitored collections.
6.6- role in split specimen collections.
6.7- chain of custody completion and finishing the collection process.
7.12- processing blind specimens.
10.1- action in case of refusals to take test.
10.2- action in "shy bladder" situations.
10.5-10.8- collector errors in tests, effects. and means of correction.

5. Collection Sites, Forms, Equipment and Supplies Used in DOT Urine Collections.

5.1 A Urine Collection for a DOT Drug Test Must Take Place in a Collection Site Meeting the Requirements of this Section. (§40.41)

5.1.1 Security Requirements. The operator of a collection site must ensure that it meets the security requirements of Section 5.2.

5.1.2 Other Requirements. 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.

5.1.3 Facility Required. The collection site must include a facility for urination described in either paragraph 5.1.4 or 5.1.5.

5.1.4 Preferred Facility. 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.

5.1.4.1 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.

5.1.4.2 The facility 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, the facility 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.

5.1.5 Other Facilities. The second type of facility for urination that a collection site may include is a multi-stall restroom.

5.1.5.1 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.

5.1.5.2 If a multi-stall restroom is used, one of the following must be done:

5.1.5.2.1 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

5.1.5.2.2 Conduct all collections in the facility as monitored collections (see Section 6.5 for procedures). This is the only circumstance in which a monitored collection may be conducted.

5.1.6 Who May Be Present. No one but the employee my 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.

5.1.7 Location Facility. A collection site my 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.

5.2 Steps Collectors and Operators of Collection Sites Must Take to Prevent Unauthorized Access That Could Compromise the Integrity of Collections. (§40.43)

5.2.1 Steps Before Each Collection.

Collectors must do the following before each collection to deter tampering with specimens:

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

5.2.1.2 Ensure that the water in the toilet is blue;

5.2.1.3 Ensure that no soap, disinfectants, cleaning agents, or other possible adulterants are present;

5.2.1.4 Inspect the site to ensure that no foreign or unauthorized substances are present;

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

5.2.1.6 Ensure that undetected access (e.g., through a door not in the collector's view) is not possible;

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

5.2.1.8 Recheck items in paragraphs 5.2.1.1 through 5.2.1.7 following each collection to ensure the site's continued integrity.

5.2.2 Steps If Facility Usually Used for Other Purposes.

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:

5.2.2.1 Access to collection materials and specimens is effectively restricted; and

5.2.2.2 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.

5.2.3 Additional Security Steps.

A collector must take the following additional steps to ensure security during the

collection process:

5.2.3.1 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 of drinking fluids in a "shy bladder" situation (see paragraph 10.2.2), the collector may conduct a collection for another employee.

5.2.3.2 To the greatest extent possible, the collector must 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.

5.2.3.3 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.

5.2.3.4 In the time between when the employee gives the collector the specimen and when the collector seals the specimen, the collector must remain within the collection site.

5.2.3.5 The collector must maintain personal control over each specimen and CCF throughout the collection process.

5.2.4 No Unauthorized Entry.

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

5.2.4.1 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 5.2.4.

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

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

5.2.4.4 The collection facility supervisor or the collector may remove any person who obstructs, interferes with, or causes a delay in the collection process.

5.2.5 Minimize Handling Specimen.

Collection site operators must minimize the number of persons handling specimens.

5.3 The Following Described Form Must Be Used to Document a DOT Urine Collection. (§40.45)

5.3.1 Required Form.

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. If an old version of the CCF is used,, the error must be corrected by a memorandum for the record. Uncorrected use of an old form will result in cancellation of the test.

5.3.2 Permitted Modifications.

The CCF may not be revised or modified, except as follows:

5.3.2.1 Other information needed for billing or other purposes necessary to the collection process may be included in the area outside the border of the form.

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

5.3.2.3 The name of the DOT agency under whose authority the test occurred may be added as part of the employer information.

5.3.2.4 A collector may use a CCF with the collector's name, address, telephone number, and fax number preprinted, but under no circumstances may the collector sign the form before the collection event.

5.3.2.5 If an employer operates through a C/TPA, the C/TPA's name and address may appear on the CCF, in which event only the employer's name and telephone number needs to appear on the CCF.

5.3.3 No Identifying Information on CCF.

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.

5.3.4 Foreign Language CCF.

An equivalent foreign-language version of the CCF approved by ODAPC may be used. Such a non-English language form may be used only in a situation where both the employee and collector understand and can use the form in that language.

5.4 Use of the CCF for Non-DOT Collections or Non-Federal Forms for DOT Collections. (§40.47)

5.4.1 CCF Can Not Be Used for Non-DOT Testing.

The CCF may not be for non-DOT urine collections. Non-Federal forms may not be used for DOT urine collections. Doing either of the foregoing subjects the Employer to enforcement action under DOT agency regulations.

5.4.1.1 In the rare case where the collector, either by mistake or as the only means to conduct a test under difficult circumstances (e.g., post-accident or reasonable suspicion test with insufficient time to obtain the CCF), uses a non-Federal form for a DOT collection, the use of a non-Federal form does not present a reason for the laboratory to reject the specimen for testing or for a MRO to cancel the result.

5.4.1.2 The use of the non-DOT form is a "correctable flaw." A MRO, to correct the problem, must follow the procedures of paragraph 10.8.2.2.

5.5 Required Test Kit. (§40.49)

For each DOT drug test, a collection kit meeting the requirements of Appendix A of this Plan must be used.

5.6 Packing Materials. (§40.51)

Materials used to send urine specimens to the laboratory.

5.6.1 Container Must Adequately Protect Specimen.

Except as provided in paragraph 5.6.2, a shipping container that adequately protects the specimen bottles from shipment damage must be used in the transport of specimens from the collection site to the laboratory.

5.6.2 No Shipping Container Required for Hand Deliveries.

A shipping container is not required if a laboratory courier hand-delivers the specimens from the collection site to the laboratory.

6. Urine Specimen Collections. (§40.6l)

6.1 Preliminary steps.

The collector must take the following steps before actually beginning a collection:

6.1.1 Failure to Appear.

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, the collector 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 paragraph 10.1.1.1).

6.1.2 Collection Process to Proceed Without Delay.

The collector must ensure that, when the employee enters the collection site, the collector begins the testing process without undue delay.

For example, the collector must not wait because the employee says he or she is not ready or is unable to urinate or because an authorized employer or employee representative is delayed in arriving.

6.1.2.1 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: 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 was 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).

6.1.2.2 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.

6.1.2.3 Urine collection must not be done by catheterization or by other means from an employee, whether conscious or unconscious, to conduct a drug test under 49 CFR Part 40. However, an employee who normally voids through self-catheterization must be informed that the employee is required to provide a specimen in that manner.

6.1.2.4 If an employee who normally voids through self-catheterization, declines to do so, this constitutes a refusal to test.

6.1.3 Employee Must Provide Positive ID.

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

6.1.4 Collector Must Provide ID.

If the employee asks, the collector must provide identification to the employee. The collector's identification must include the collector's name and the collector's employer's name, but does not have to include a picture, address, or telephone number.

6.1.5 Collector Explains Procedure.

The collector must explain the basic collection procedure to the employee, including showing the employee the instructions on the back of the CCF.

6.1.6 Employee Must Remove Outer Clothing.

The collector must 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 the collector's directions constitutes a refusal to test.

6.1.6.1 If the employee asks for a receipt for any belongings left with the collector, the collector must provide one.

6.1.6.2 The collector must allow the employee to keep his or her wallet.

6.1.6.3 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).

6.1.6.4 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.

6.1.6.5 If, the collector in his or her duties under paragraph 6.1.6.4 finds any material that could be used to tamper with a specimen, the collector must:

6.1.6.5.1 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 Section 6.4); or

6.1.6.5.2 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.

6.1.7 Medications Not to Be Listed on CCF.

The employee must be instructed 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.)

6.2 The Following Steps Must Be Taken Before the Employee Provides the Urine Specimen. (§40.63)

6.2.1 Complete Step 1 of the CCF.

6.2.2 Wash Hands.

The collector shall instruct the employee to wash and dry his or her hands at this time. The collector shall also tell the employee not to wash his or her hands again until after delivering the specimen to the collector. The collector must not give the employee any further access to water or other materials that could be used to adulterate or dilute a specimen.

6.2.3 Select a Container.

The collector shall 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.

6.2.4 Provide Specimen.

The employee shall be directed 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 voiding.

6.2.4.1 Except in the case of an observed or a monitored collection (see Sections 6.4 and 6.5), neither the collector nor anyone else may go into the room with the employee.

6.2.4.2 The collector may set a reasonable time limit for voiding.

6.2.5 Collector Must Pay Attention.

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 Section 6.4) 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.

6.3 What the Collector Must Check. (§40.65)

The collector must check the following when the employee gives the collection container to the collector:

6.3.1 Sufficiency of Specimen.

The specimen must contain at least 45 mL of urine.

6.3.1.1 If it does not, the "shy bladder" procedures must be followed (see paragraph 10.2.2).

6.3.1.2 When the "shy bladder" procedures are used, the original specimen must be discarded, unless another problem (i.e., temperature out of range, signs of tampering) also exists.

6.3.1.3 The combination of urine collected from separate voids to create a specimen is never permitted.

6.3.1.4 Discard any excess urine.

6.3.2 Temperature.

The temperature of the specimen must be checked no later than four minutes after the employee has given the collector the specimen.

6.3.2.1 The acceptable temperature range is 32-38 C / 90-100 F.

6.3.2.2 The collector shall determine the temperature of the specimen by reading the temperature strip attached to the collection container.

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

6.3.2.4 If the specimen temperature is outside the acceptable range, the collector must mark the "No" box and enter in the "Remarks" line (Step 2) the collector's findings about the temperature.

6.3.2.5 If the specimen temperature is outside the acceptable range, the collector must immediately conduct anew collection using direct observation procedures (see Section 6.4).

6.3.2.6 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.

6.3.2.7 In a case where the employee refuses to provide another specimen (see paragraph (10.1.1.3) or refuses to provide another specimen under direct observation (see paragraph 10.1.1.4), the collector must notify the DER. As soon as the DER has been notified, any specimen the employee has provided previously during the collection procedure must be discarded.

6.3.3 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., any unusual odor).

6.3.3.1 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 Section 6.4).

6.3.3.2 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 shows signs of tampering. The collector shall 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.

6.3.3.3 In a case where the employee refuses to provide another specimen (see paragraph 10.1.1.3) or refuses to provide a specimen under direct observation (see paragraph 10.1.1.4), the collector must notify the DER.

As soon as the collector has notified the DER, the collector must discard any specimen the employee has provided previously during the collection

6.4 Directly Observed Collection. (§40.67)

6.4.1 When Required. An immediate collection under direct observation with no advance notice to the employee, is required if:

6.4.1.1 The laboratory reported to the MRO that a specimen is invalid, and the MRO reported to the Employer that there was not an adequate medical explanation for the result;

6.4.1.2 The MRO reported to the Employer that the original positive, adulterated, or substituted result had to be cancelled because the test of the split specimen could not be performed; or

6.4.1.3 The laboratory reported to the MRO that the specimen was negative-dilute with a creatinine concentration greater than or equal to 2 mg/dL but less than or equal to 5 mg/dL, and the MRO reported the specimen to the Employer as negative-dilute and that a second collection must take place under direct observation.

6.4.2 Other Circumstances When Required. A collection under direct observation of an employee may be required by the DER if the drug test is a return-to-duty test or a follow-up test.

6.4.3 Direct Collection. A collector shall immediately conduct a collection under direct observation if:

6.4.3.1 The DER requires a direct collection to do so (see paragraphs 6.4.1 and 6.4.2); or

6.4.3.2 The collector observed materials brought to the collection site or the employee's conduct clearly indicates an attempt to tamper with a specimen (see 6.1.6.5.1 and 6.2.5); or

6.4.3.3 The temperature on the original specimen was out of range (see 6.3.2.5); or

6.4.3.4 The original specimen appeared to have been tampered with (see 6.3.3.1).

6.4.4 Explain Reason to Employee. The employer must explain to the employee the reason for a directly observed collection under paragraph 6.4.1 or 6.4.2. The collector must explain to the employee the reason under 49 CFR Part 40 for a directly observed collection under paragraphs 6.4.3.2 through 6.4.3.4.

6.4.5 Use New CCF. The collector must complete a new CCF for the directly observed collection.

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

6.4.5.2 The collector must check the "Observed, (Enter Remark)" box and

enter the reason (see 6.4.2) in the "Remarks" line (Step 2).

6.4.6 Procedure If Two (2) Specimens Sent to Lab. 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, the collector shall 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.

6.4.7 Observer Must Be of Same Gender. The collector must ensure that the observer is the same gender as the employee. The collector must never permit an opposite gender person to act as the observer. The observer can be a different person from the collector and need not be a qualified collector.

6.4.8 Instruction to Observer. If someone else is to observe the collection (e.g., in order to ensure a same gender observer), the collector must verbally instruct that person to follow procedures at paragraphs 6.4.9 and 6.4.10. If the collector is the observer, the collector also must follow these procedures.

6.4.9 Observer's Duties. The observer must watch the employee urinate into the collection container. Specifically, the observer must watch the urine go from the employee's body into the collection container.

6.4.10 Observer Must Not Take Specimen from Employee. The observer, if 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.

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

6.4.12 Employee Refusal to Allow Observation is Refusal to Test. If the employee declines to allow a directly observed collection required or permitted under this section to occur, this is a refusal to test.

6.5 Monitored Collections. (§40.69)

6.5.1 Secure Room. 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.

6.5.2 Monitor Must Be Same Gender. 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). The monitor can be a different person from the collector and need not be a qualified collector.

6.5.3 Instructions to Monitor.

The collector, if someone else is to monitor the collection (e.g., in order to ensure a same gender monitor), must verbally instruct that person to follow procedures at paragraphs 6.5.4 and 6.5.5. If the collector is the monitor, the collector too must follow these procedures.

6.5.4 Monitor Must Not Watch.

The monitor must not watch the employee urinate into the collection container. If the monitor hears sounds or makes other observations indicating an attempt to tamper with a specimen, there must be an additional collection under direct observation (see 6.2.5, 6.3.3 and 6.4.3.2).

6.5.5 Monitor Must Ensure Container Taken Directly to Collector.

The monitor must ensure that the employee takes the collection container directly to the collector as soon as the employee has exited the enclosure.

6.5.6 Monitor's Name on CCF.

When someone other than the Collector has acted as the monitor, the Collector must note that person's name in the "Remarks" line of the CCF (Step 2).

6.5.7 Employee's Refusal to Allow Monitored Collection is Refusal to Test.

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

6.6 Preparation of the Specimens. (§40.7l)

6.6.1 Split Specimen Required.

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

6.6.2 Steps after Specimen Given to Collector.

The collector must take the following steps, in order, after the employee brings the urine specimen to the collector. These steps must be taken in the presence of the employee.

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

6.6.2.2 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.

6.6.2.3 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.

6.6.2.4 The collector, not the employee, must place and secure (i.e., tighten or snap) the lids/caps on the bottles.

6.6.2.5 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.

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

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

6.6.2.8 The collector must discard any urine left over in the collection container after both specimen bottles have been appropriately filled and sealed.

6.7 Completion of the Collection Process. (§40.73)

6.7.1 Steps to Complete Collection Process.

The collector must do the following things to complete the collection process. The collector must complete the steps called for in paragraphs 6.7.1.1 through 6.7.1.7 in the employee's presence.

6.7.1.1 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, the collector 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, the collector must, at a minimum, print the employee's name in the appropriate place.

6.7.1.2 Complete the chain of custody on the CCF (Step 4) by printing the collector's name (note: the collector's name may be pre-printed), 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.

6.7.1.3 Ensure that all copies of the CCF are legible and complete.

6.7.1.4 Remove Copy 5 of the CCF and give it to the employee.

6.7.1.5 Place the specimen bottles and Copy 1 of the CCF in the appropriate pouches of the plastic bag.

6.7.1.6 Secure both pouches of the plastic bag.

6.7.1.7 Advise the employee that he or she may leave the collection site.

6.7.1.8 Prepare the sealed plastic bag containing the specimens and CCF for shipment. The collector must:

6.7.1.8.1 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 multiple collections are being made.)

6.7.1.8.2 Seal the container as appropriate.

6.7.1.8.3 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.

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

6.7.2 Specimen Must Be Shipped as Quickly as Possible.

The collector or collection site must ensure that each specimen collected is shipped to a laboratory as quickly as possible, but in any case within 24 hours or during the next business day.

7. Drug Testing Laboratories.

7.1 Approved Laboratories for DOT Testing. (§40.8l)

7.1.1 HHS Certification Required.

A drug testing laboratory located in the U.S. is permitted to participate in DOT drug testing only if it is certified by HHS under the National Laboratory Certification Program (NLCP) for all testing required under 49 CFR Part 40.

7.1.2 Laboratories in Canada and Mexico.

A drug testing laboratory located in Canada or Mexico which is not certified by HHS under the NLCP is permitted to participate in DOT drug testing only if:

7.1.2.1 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 49 CFR Part 40; or

7.1.2.2 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 the laboratory under those equivalent standards and procedures.

7.1.3 Laboratory Must Comply with 49 CFR Part 40.

A laboratory participating in the DOT drug testing program must comply with the requirements of 49 CFR Part 40. The laboratory must also comply with all applicable requirements of HHS in testing DOT specimens, whether or not the HHS requirements are explicitly stated in 49 CFR Part 40.

7.1.4 Laboratory Subject to PIE Procedure.

If DOT determines that a laboratory is in noncompliance with 49 CFR Part 40, it could be subject to PIE proceedings under Subpart R of 49 CFR Part 40. If the Department issues a PIE with respect to a laboratory, that laboratory is ineligible to participate in the DOT drug testing program even if it continues to meet the requirements of paragraph 7.1.1 or 7.1.2 of this section.

7.2 Laboratory Processing of Incoming Specimens. (§40.83)

7.2.1 Only Lab Copy of CCF May Be Sent to Lab.

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.

7.2.2 HHS Guidelines Must Be Followed.

The laboratory must comply with applicable provisions of the HHS guidelines concerning accessioning and processing urine drug specimens.

7.2.3 Inspect for "Fatal Flaws."

The laboratory must inspect each specimen and CCF for the following "fatal flaws:"

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

7.2.3.2 The specimen bottle seal is broken or shows evidence of tampering, unless a split specimen can be re-designated (see paragraph 7.2.7);

7.2.3.3 The collector's printed name and signature are omitted from the CCF; and

7.2.3.4 There is an insufficient amount of urine in the primary bottle for analysis, unless the specimens can be re-designated (see paragraph 7.2.7).

7.2.4 Procedure If "Fatal Flaw" Found.

When the laboratory finds a specimen meeting the criteria of paragraph 7.2.3, it must document its findings and stop the testing process. Report the result in accordance with paragraph 7.1.3.

7.2.5 Inspect for "Correctable Flaws."

The laboratory must inspect each specimen and CCF for the following "correctable flaws:"

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

7.2.5.2 The collector's signature is omitted on the certification statement on the CCF.

7.2.6 Procedure If "Correctable Flaw" Found.

Upon finding that a specimen meets the criteria of paragraph 7.2.5, the laboratory shall document the flaw and continue the testing process.

7.2.6.1 In such a case, the laboratory must retain the specimen for a minimum of 5 business days from the date on which it initiated action to correct the flaw.

7.2.6.2 The laboratory must then attempt to correct the flaw by following the procedures of paragraph 10.8.2.

7.2.6.3 If the flaw is not corrected, the laboratory shall report the result in accordance with paragraph 7.1.3.

7.2.7 Procedure If Split Specimen Missing.

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, test the primary specimen and follow appropriate procedures

outlined in paragraph 9.3.2 regarding the unavailability of the split specimen for testing.

7.2.7.1 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:

7.2.7.1.1 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

7.2.7.1.2 The primary specimen is labeled as Bottle B, and the split specimen as Bottle A; or

7.2.7.1.3 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

7.2.7.1.4 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.

7.2.7.2 In situations outlined in paragraph 7.2.7.1, 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.

7.2.8 Note Flaws on CCF.

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.

7.3 Laboratory Must Test for the Following Five Drugs or Classes of Drugs in a DOT Drug Test. (§40.85)

The laboratory must not test "DOT specimens" for any other drugs.

7.3.1 Marijuana Metabolites.

7.3.2 Cocaine Metabolites.

7.3.3 Amphetamines.

7.3.4 Opiate Metabolites.

7.3.5 Phencyclidine (PCP).

7.4 Cutoff Concentrations for Initial and Confirmation Tests. (§40.87)

7.4.1 Cutoff Concentrations for Initial and Confirmation Tests.

A laboratory must use the cutoff concentrations displayed in the following table for initial and confirmation drug tests. All cutoff concentrations are expressed in nanograms per milliliter (ng/mL).

TYPE OF DRUG OR METABOLITE	INITIAL TEST	CONFIRMATION TEST
Marijuana metabolites (I) Delta-9-tatrahydrocannabinol-9-–carboxylic acid (THC)	50	15
Cocaine metabolites (Benzoylecgonine)	300	150
Phencyclidine (PCP)	25	25
Amphetamines	1000	
(I) Amphetamine		500
(ii) Methamphetamine		500 (Specimen must also contain amphetamine at a concentration of greater than or equal to 200 ng/mL).
Opiate Metabolites	2000	
(I) Codeine		2000
(ii) Morphine		2000
(iii) 6-acetylmorphine (6-AM)		10 (Test for 6-AM in the specimen. Conduct this test only when specimen contains morphine at a concentration greater than or equal to 2000 ng/mL.

7.4.2 Reporting Initial Results.

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.

7.4.3 Reporting Confirmatory Results.

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.

7.4.4 Reporting Morphine and Codeine.

The laboratory must report quantitative values for morphine or codeine at 15,000 ng/mL or above.

7.5 Validity Testing. (§40.89)

7.5.1 Defined.

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.

7.5.2 Validity Testing Required.

A laboratory must conduct validity testing after HHS issues final rules. Until then validity testing is voluntary.

7.6 Validity Tests Which Laboratories Must Conduct on Primary Specimens. (§40.9l)

7.6.1 Test for Creatinine.

The laboratory must determine the creatinine concentration on each primary specimen. The laboratory must also determine its specific gravity if it finds the creatinine concentration to be less than 20 mg/dL.

7.6.2 Measure pH.

The laboratory must determine the pH of each primary specimen.

7.6.3 Test for Adulterants.

The laboratory must perform one or more validity tests for oxidizing adulterants on each primary specimen.

7.6.4 Procedures For Additional Validity Tests.

The laboratory must perform additional validity tests on the primary specimen when the following conditions are observed:

7.6.4.1 Abnormal physical characteristics;

7.6.4.2 Reactions or responses characteristic of an adulterant obtained during initial or confirmatory drug tests (e.g., on-recovery of internal standards, unusual response); or

7.6.4.3 Possible unidentified interfering substance or adulterant.

7.6.5 Procedure For Testing at Another HHS Laboratory.

If the laboratory determines that the specimen is invalid and HHS guidelines direct the laboratory to contact the MRO, the laboratory must contact the MRO and together decide if testing the primary specimen by another HHS certified laboratory would be useful in being able to report a positive or adulterated test result.

7.7 Criteria to Establish That a Specimen Is Dilute or Substituted. (§40.93)

7.7.1 Definition of Dilute Specimen.

A laboratory must consider the primary specimen to be dilute when the creatinine concentration is greater than or equal to 2 mg/dL but less than 20 mg/dL and the specific gravity is greater than 1.0010 but less than 1.0030 on a single aliquot.

7.7.2 Definition of Substituted Specimen.

A laboratory must consider the primary specimen to be substituted when the creatinine concentration is less than 2 mg/dL or equal to 5 mg/dL and the specific gravity is less than or equal to 1.0010 or greater than or equal to 1.0200 on both the initial and confirmatory creatinine tests and on both the initial and confirmatory specific gravity tests on two separate aliquots.

7.8 Criteria to Establish That a Specimen Is Adulterated. (§40.95)

7.8.1 Definition of Adulterated Specimen.

A laboratory must consider the primary specimen to be adulterated if it determines that:

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

7.8.1.2 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

7.8.1.3 The physical characteristics of the specimen are outside the normal expected range for human urine.

7.8.2 HHS Guidance to Be Used.

In making a determination under paragraph 7.8.1, the laboratory must apply the criteria in current HHS requirements or specimen validity guidance.

7.9 Laboratory Reports. (§40.97)

7.9.1 Categories.

A laboratory must report the results for each primary specimen tested as one of the following:

7.9.1.1 Negative;

7.9.1.2 Negative-dilute, with numerical values for creatinine and specific gravity;

7.9.1.3 Rejected for testing, with remark(s);

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

7.9.1.5 Positive, with drug(s)/metabolite(s) noted - dilute;

7.9.1.6 Adulterated, with numerical values (when applicable), with remark(s);

7.9.1.7 Substituted, with numerical values for creatinine and specific gravity; or

7.9.1.8 Invalid result, with remark(s).

7.9.2 Lab Reports Only to MRO. A laboratory must report laboratory results directly, and only, to the MRO at his or her place of business. A laboratory must not report results to or through the DER or a service agent (e.g., C/TPA).

7.9.2.1 Negative results: 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, or the laboratory results report may be provided electronically (i.e., computer data file).

7.9.2.1.1 If the laboratory elects to provide the laboratory results report, it must include the following elements, as a minimum, in the report format:

7.9.2.1.1.1 Laboratory name;

7.9.2.1.1.2 Employer's name (I.D. or account number may

be included);
7.9.2.1.1.3 Specimen I.D. number;
7.9.2.1.1.4 Donor's SSN or employee I.D. number, if provided;
7.9.2.1.1.5 Reason for test, if provided;
7.9.2.1.1.6 Date of the collection;
7.9.2.1.1.7 Date received at the laboratory;
7.9.2.1.1.8 Date certifying scientist released the results;
7.9.2.1.1.9 Results (e.g., positive, adulterated) as listed in paragraph 7.9.1; and
7.9.2.1.1.10 Remarks section, with an explanation of any situation in which a correctable flaw has been corrected.

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

7.9.2.1.3 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.

7.9.2.2 Non-negative Results. The laboratory 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 7.9.2.1.1 and 7.9.2.1.2.

7.9.3 Information to Be Protected from Unauthorized Access. 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.

7.9.4 Results Must Be Timely Sent to MRO. 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.

7.9.5 Results Lab Must Provide Positive, Adulterated, and Substituted Test Results.

7.9.5.1 The laboratory must provide quantitative values for confirmed positive drug test results to the MRO when the MRO requests the laboratory to do so in writing. The MRO' s request may either be a general request covering all such results the laboratory sends to the MRO or a specific case-by-case request.

7.9.5.2 The laboratory must provide the numerical values that support the adulterated (when applicable) or substituted result, without a request from the MRO. The laboratory must also provide to the MRO numerical values for creatinine and specific gravity for the negative-dilute test result,

without a request from the MRO.

7.9.6 Results Lab Must Provide Morphine or Codeine Results at 15,000 ng/mL or above. The laboratory must provide quantitative values for confirmed opiate results for morphine or codeine at 15,000 ng/mL or above, even if the MRO has not requested quantitative values for the test result.

7.10 Laboratory Specimen Retention. (§40.99)

7.10.1 Primary Specimen. A 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.

7.10.2 Storage Requirements. The laboratory must keep such a specimen in secure, long-term, frozen storage in accordance with HHS requirements.

7.10.3 Additional Retention Period May Be Requested. Within the one-year period, the MRO, the employee, the employer, 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, the laboratory must comply with it. If no such request is received, the laboratory may discard the specimen at the end of the year.

7.10.4 Untested Split Specimen Retention.

If the laboratory has not sent 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 laboratory retains the primary specimen and under the same storage conditions.

7.10.5 Tested Split Specimen Retention.

The laboratory testing the split specimen must meet the requirements of paragraphs 7.10.1 through 7.10.4 with respect to the split specimen.

7.11 Prohibited Relationships Between a Laboratory and a MRO. (§40.l 0l)

7.11.1 No Conflict of Interest.

A 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.

7.11.2 Examples of Conflicts of Interest.

The following are examples of relationships between laboratories and MROs that the DOT 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:

7.11.2.1 The laboratory employs an MRO who reviews test results produced by the laboratory;

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

7.11.2.3 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;

7.11.2.4 The laboratory gives the employer a discount or other incentive to use a particular MRO;

7.11.2.5 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

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

7.12 Blind Specimens. (§40.103)

7.12.1 Who Is Not Required to Send Blind Specimens.

An employer or C/TPA, who has an aggregate of fewer than 2,000 DOT-covered employees, is not required to provide blind specimens.

7.12.2 Who Must Send Blind Specimens.

An employer or C/TPA with an aggregate of 2,000 or more DOT-covered employees must send blind specimens to the laboratories it uses. An employer or C/TPA must transmit to each laboratory to which it sends at least 100 specimens in a year a number of blind specimens equivalent to one percent of the specimens it sent to that laboratory, up to a maximum of 50 blind specimens in each quarter (i.e., January-March, April-June, July-September, October-December). A C/TPA must apply this percentage to the total number of DOT-covered employees' specimens it sends to the laboratory. The blind specimen submissions must be evenly spread throughout the year. The following examples illustrate how this requirement works:

Example 1. An employer sends 2,500 specimens to Lab X in Year 1. In this case, the employer would send 25 blind specimens to Lab X in Year 1. To meet the even distribution requirement, 6 would be sent in each of three quarters and 7 in the other.

Example 2. An employer sends 2,000 specimens to Lab X and 1,000 specimens to Lab Y in Year 1. In this case, the employer 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. Same as Example 2, except that 20 specimens are also sent to Lab Z. In this case, the employer would send blind specimens to Labs X and Y as in Example 2. No blind specimens would have to be sent to Lab Z, because fewer than 100 specimens were sent to Lab Z.

Example 4. A C/TPA sends 2,000 specimens to Lab X in Year 1. These 2,000 specimens represent 200 small employers who have an average of 10 covered employees each. In this case the C/TPA - not the individual employers - send 20 blind specimens to Lab X in Year 1, again ensuring even distribution. The individual employers are not required to provide any blind specimens on their own.

Example 5. A 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 the C/TPA need send only 50 blind specimens per quarter, rather than the 100 per quarter it would have to send to meet the one percent rate. The annual total would be 200, rather than 400, blind specimens.

7.12.3 Make up of Blind Specimens.

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 paragraph 7.7.2).

7.12.3.1 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.

7.12.3.2 The supplier must provide information regarding the shelf life of the blind specimens.

7.12.3.3 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.

7.12.3.4 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.

7.12.3.5 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.

7.12.3.6 If the blind specimen is substituted, the creatinine must be less than or equal to 2, and the specific gravity must be 1.0.

7.12.4 Blind Specimen Must Be Indistinguishable.

Each blind specimen must be indistinguishable to the laboratory from a normal specimen.

7.12.4.1 The blind specimens must be submitted to the laboratory using the same channels (e.g., via a regular collection site) through which employees' specimens are sent to the laboratory.

7.12.4.2 The collector must use a CCF, place fictional initials on the specimen bottle label/seal, indicate for the MRO on Copy 2 that the specimen is a blind specimen, arid discard Copies 4 and 5 (employer and employee copies).

7.12.4.3 All blind specimens must include split specimens.

7.13 Procedure When the Laboratory Reports a Result Different from That Expected for a Blind Specimen. (§40.l05)

7.13.1 Sender Must Investigate.

If the result reported to the MRO for a blind specimen is different from the result

expected, the party submitting the blind specimen must investigate the discrepancy.

7.13.2 False Negative.

If the unexpected result is a false negative, the party submitting the blind specimen 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.

7.13.3 False Positive.

If the unexpected result is a false positive, the party submitting the blind specimen 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 party submitting the blind specimen must also notify ODAPC of the discrepancy by telephone (202-366-3784) or e-mail (addresses are listed on the ODAPC web site, http://www.dot.gov/ost/dapc). ODAPC will notify HHS who will take appropriate action.

7.14 Labs Must Permit Inspection. (§40.107)

Laboratories 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.

7.15 Laboratory Documentation. (§40.l09)

7.15.1 Records Regarding Specimens.

A laboratory must retain all records pertaining to each employee urine specimen for a minimum of two years.

7.15.2 Employer Specific Data.

A laboratory must also keep for two years employer-specific data required in 7.16.

7.15.3 Additional Retention Time May Be Requested.

Within the two-year period, the MRO, the employee, the employer, or a DOT agency may request in writing that the laboratory 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, it must comply with it. If the laboratory does not receive such a request, it may discard the records at the end of the two-year period.

7.16 Laboratory Statistical Summaries. (§40.111)

7.16.1 Semi-Annual Report.

A laboratory must transmit an aggregate statistical summary, by employer, of the data listed in Appendix B to 49 CFR Part 40 to the employer on a semi-annual basis.

7.16.1.1 The summary must not reveal the identity of any employee.

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

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

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

7.16.2 Report Requested in Response to Audit. When the employer requests a summary in response to an inspection, audit, or review by a DOT agency, the laboratory must provide it unless the employer had fewer than five aggregate test results. In that case, the laboratory must send the employer 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.

7.16.3 Information must Be Released to Appropriate Parties. Information must also be released to appropriate parties as provided in Sections 17.4 and 17.5.

7.17 Additional Information. (§40.113)

Additional information concerning laboratories in the following sections:

1.3 - definition.
4.1- conflicts of interest concerning collectors.
5.4- laboratory rejections of test for improper form.
8.3 - conflicts of interest concerning MROs.
9.3 - role of first laboratory in split specimen tests.
9.4 - role of second laboratory in split specimen tests (drugs).
9.5 - role of second laboratory in split specimen tests (adulterants).
9.6 - role of second laboratory in split specimen tests (substitution).
9.7-9.8 - transmission of split specimen test results to MRO.
10.6-10.8 - role in correcting errors.
12.6 - prohibition on making specimens available for other purposes.
17.4 - release of information to employees.
17.5 - limits on release of information.
18.8 - role with respect to other service agents.

8. Medical Review Officers and the Verification Process.

8.1 Qualifications to Act as an MRO in the DOT Drug Testing Program. (§40.121)

8.1.1 Credentials. A MRO must be a licensed physician (Doctor of Medicine or Osteopathy). A licensed physician in any U.S., Canadian, or Mexican jurisdiction and who meets the other requirements of this section, is authorized to perform MRO services with respect to all covered employees, wherever they are located. For example, a physician licensed as an M.D. in one state or province in the U.S., Canada, or Mexico, 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.

8.1.2 Basic Knowledge. A MRO must be knowledgeable in the following areas:

8.1.2.1 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.

8.1.2.2 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.

8.1.2.3 MRO must be knowledgeable about 49 CFR Part 40, the DOT MRO Guidelines, and the DOT agency regulations applicable to the employers for whom the MRO evaluates drug test results, and the MRO must keep current on any changes to these materials. The DOT MRO Guidelines document is available from ODAPC (Department of Transportation, 400 7th Street, SW., Room 10403, Washington DC, 20590, 202-366-3784, or on the ODAPC web site (http://www.dot.gov/ost/dapc)).

8.1.3 Qualification Training. A MRO must receive qualification training meeting the following requirements:

8.1.3.1 Qualification training must provide instruction on the following subjects:

8.1.3.1.1 Collection procedures for urine specimens;

8.1.3.1.2 Chain of custody, reporting, and record keeping;

8.1.3.1.3 Interpretation of drug and validity tests results;

8.1.3.1.4 The role and responsibilities of the MRO in the DOT drug testing program;

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

8.1.3.1.6 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 49 CFR Part 40 and DOT agency rules.

8.1.3.2 Following completion of qualification training under paragraph 8.1.3.1, a 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 8.1.3.1.

8.1.4 Schedule for Qualification Training.

8.1.4.1 Those who became an MRO before August 1, 2001, and have already met the qualification training requirement do not have to meet it again.

8.1.4.2 Those who became a MRO before August 1, 2001, but have not yet met the qualification training requirement must do so no later than January 31, 2003.

8.1.4.3 Those who become a MRO on or after August 1, 2001 must meet the qualification training requirement before beginning to perform MRO functions.

8.1.5 Continuing Education. During each three-year period from the date on which a MRO satisfactorily completes the examination under paragraph 8.1.3.2 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.

8.1.5.1 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.

8.1.5.2 The MRO continuing education activities must include assessment tools to assist in determining whether the MRO has adequately learned the material.

8.1.6 Documentation.

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

8.2 A MRO Has the Following Responsibilities. (§40.123)

8.2.1 Impartial Gate Keeper.

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

8.2.2 Quality Assurance.

Providing a quality assurance review of the drug testing process for the specimens under the MRO's purview. This includes, but is not limited to:

8.2.2.1 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 Sections 10.5 - 10.7). A MRO is not required to review laboratory internal chain of custody documentation. No one is permitted to cancel a test because a MRO has not reviewed this documentation;

8.2.2.2 Providing feedback to employers, collection sites and laboratories regarding performance issues where necessary; and

8.2.2.3 Reporting to and consulting with the ODAPC or a relevant DOT agency when the MRO wishes DOT assistance in resolving any program issue. Employers or service agents are prohibited from limiting or attempting to limit the MRO's access to DOT for this purpose and from retaliating in any way against a MRO for discussing drug testing issues with DOT.

8.2.3 Determination of Legitimate Medical Explanation.

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

8.2.4 No Doctor-Patient Relationship.

While a MRO provides medical review of employees' test results, 49 CFR Part 40 does not deem that the MRO has established a doctor-patient relationship with the employee whose test the MRO reviews.

8.2.5 Investigate and Correct Problems.

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).

8.2.6 Ensure Timely Flow of Test Results.

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

8.2.7 Protect Confidentiality.

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

8.2.8 Comply with Applicable Regulations.

The MRO must perform all functions in compliance with 49 CFR Part 40 and other DOT agency regulations.

8.3 No Conflict of Interest. (§40.125)

A 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 the MRO's responsibilities to that employer. A 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 paragraph 7.11.2.

8.4 Negative Test Results. (§40.127)

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:

8.4.1 Review Copy 2.

Review Copy 2 of the CCF to determine if there are any fatal or correctable errors that may require the MRO to initiate corrective action or to cancel the test (see Sections 10.5 and 10.7).

8.4.2 Review Negative Results.

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

8.4.3 Information MRO Must Have Before Reporting Negative Results.

Before the MRO reports a negative test result, the MRO must have possession of the following documents:

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

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

8.4.4 Legible Copy.

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.

8.4.5 Mark Copy 2.

On Copy 2 of the CCF, the MRO must 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.

8.4.6 Report in a Confidential Manner.

Report the result in a confidential manner (see Sections 8.19 - 8.21).

8.4.7 MRO Responsibility for Staff Work.

Staff under the MRO's direct, personal supervision may carry out the administrative functions of this section for the MRO, but only the MRO can cancel a test.

8.4.7.1 On specimen results that are reviewed by the MRO's staff, the MRO is responsible for assuring the quality of their work.

8.4.7.2 The MRO is required to personally review at least 5 percent of all CCFs reviewed by the MRO's 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.

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

8.4.7.4 The MRO must make these CCFs easily identifiable and

retrievable by the MRO for review by DOT agencies.

8.5 MRO Functions in Reviewing Laboratory Confirmed Positive, Adulterated, Substituted, or Invalid Drug Test Results. (§40.129)

8.5.1 Positive, Adulterated, Substituted, or Invalid Drug Tests.

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:

8.5.1.1 Review Copy 2 of the CCF to determine if there are any fatal or correctable errors that may require cancellation of the test (see Sections 10.5 and 10.7). Staff under the MRO's direct, personal supervision may conduct this administrative review, but only the MRO may verify or cancel a test.

8.5.1.2 Review Copy 1 of the CCF and ensure that it is consistent with the information contained on Copy 2, that the test result is legible, and that the certifying scientist signed the form. 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).

8.5.1.3 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.

8.5.1.4 Except in the circumstances spelled out in Section 8.7, 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.

8.5.1.5 Verify the test result as either negative, positive, test cancelled, or refusal to test because of adulteration or substitution, consistent with the requirements of Sections 8.8, 8.12 and 8.17.

8.5.2 Information the MRO Must Have Before Reporting Test Result.

Before the MRO reports a verified negative, positive, test cancelled, refusal to test because of adulteration or substitution, the MRO must have in possession the following documents:

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

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

8.5.3 Mark CCF - Positive Test.

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) or metabolite(s) detected on the "Remarks" line, sign and date the verification statement.

8.5.4 Report in a Confidential Manner.

Report the result in a confidential manner (see Sections 8.19 - 8.21).

8.5.5 Mark CCF - Adulterated, Substituted, or Invalid Drug Tests.

With respect to adulterated, substituted, or invalid drug tests 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.

8.5.6 Interrelation of Stand down Procedure.

The MRO's actions concerning reporting confirmed positive, adulterated, or substituted results to the employer before the MRO has completed the verification process are also governed by the stand-down provisions of paragraph 2.7.2.

8.5.6.1 If an employer has a stand-down policy that meets the requirements of paragraph 2.7.2, the MRO may report to the DER that the MRO has received an employee's laboratory confirmed positive, adulterated, or substituted test result, consistent with the terms of the waiver the employer received. The MRO must not provide any further details about the test result (e.g., the name of the drug involved).

8.5.6.2 If the employer does not have a stand-down policy that meets the requirements of paragraph 2.7.2, the MRO must not inform the employer that the MRO has received an employee's laboratory confirmed positive, adulterated, or substituted test result until the MRO has verified the test result. For example, a MRO employed directly by an Employer must not tell anyone on the Employer's staff or management that the MRO has received an employee's laboratory confirmed test result.

8.6 MRO or DER Notification of an Employee of the Verification Process after a Confirmed Positive, Adulterated, Substituted, or Invalid Test Result. (§40.131)

8.6.1 MRO Must Contact Employee Directly.

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.

8.6.2 MRO's Staff's Role.

The MRO staff under the MRO's personal supervision may conduct this initial contact.

8.6.2.1 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 with the MRO, the staff person must document the employee's decision, including the date and time.

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

8.6.2.3 A staff person may advise an employee to have medical information (e.g., prescriptions, information forming the basis of a

legitimate medical explanation for a confirmed positive test result) ready to present at the interview with the MRO.

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

8.6.3 Required Efforts to Contact Employee.

The MRO, or the MRO's 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 the MRO's staff cannot reach the employee directly after making these efforts, the MRO or the MRO's staff must take the following steps:

8.6.3.1 Document the efforts made to contact the employee, including dates and times. If both phone numbers are incorrect (e.g., disconnected, wrong number), the MRO may take the actions listed in paragraph 8.6.3.2 without waiting the full 24-hour period.

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

8.6.3.2.1 The DER must simply be directed to inform the employee to contact the MRO.

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

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

8.6.4 DER Assistance in Contacting Employee.

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 must inform the employee that he or she must contact the MRO within the next 72 hours and tell the employee the consequences of failing to do so (see paragraph 8.7.1.2).

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

8.6.4.2 If the DER has 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.

8.6.4.2.1 The DER must document the dates and times of these efforts.

8.6.4.2.2 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.

8.7 Circumstances Under Which the MRO May Verify a Test as Positive, or as a Refusal to Test Because of Adulteration or Substitution, Without Interviewing the Employee. (§40.133)

8.7.1 When a Positive Can Be Confirmed Without Contacting the Employee.

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 Section 8.8 - 8.12. However, there are three circumstances in which the MRO may verify such a result without an interview:

8.7.1.1 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.

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

8.7.1.3 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.

8.7.2 MRO Documentation.

The MRO, when verifying a test result as a positive or refusal to test under this section must document the date, time and reason, following the instructions in Section 8.19.

8.7.3 Late Information from the Employee.

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 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.

8.8 What the MRO must Tell the Employee at the Beginning of the Verification Interview. (§40.l35)

8.8.1 Test Result.

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.

8.8.2 Explain Verification Interview Process.

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

8.8.3 Explanation of Further Medical Evaluation.

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.

8.8.4 Warn Employee of MRO's Duty to Disclose.

The MRO must warn an employee who has a confirmed positive, adulterated, substituted or invalid test that the MRO is required to provide to third parties drug test result information and medical information affecting the performance of safety-sensitive duties that the employee gives the MRO in the verification process without the employee's consent (see Section 17.3).

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

8.8.4.2 For purposes of this paragraph 8.8.4, 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.

8.8.4.3 For purposes of this paragraph 8.8.4, 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 paragraph 16.7.7), DOT, another Federal safety agency (e.g., the NTSB), or any state safety agency as required by state law.

8.8.5 MRO Will Contact Employee's Doctor If Employee Consents.

The MRO must also advise the employee that, before informing any third party about any medication the employee is using pursuant to a legally valid prescription under the Controlled Substances Act, the MRO will, if the employee consents, contact the prescribing physician to determine if the medication can be changed to one that does not make the employee medically unqualified or does not pose a significant safety risk.

8.9 Basis for the MRO to Verify Test Results Involving Marijuana, Cocaine, Amphetamines, or PCP. (§40.137)

8.9.1 MRO Must Confirm Unless Legitimate Employee Explanation.

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) or metabolite(s) in his or her system.

8.9.2 Employee Must Have a Chance to Provide Legitimate Explanation.

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

8.9.3 Employee Has Burden of Proof.

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.

8.9.4 MRO Determination.

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.

8.9.5 Factors MRO May Consider.

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:

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

8.9.5.2 There can be a legitimate medical explanation only with respect to a substance that has a legitimate medical use. Use of a drug of abuse (e.g., heroin, PCP, marijuana) or any other substance (see paragraphs 8.14.6 and 8.14.7) 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.

8.9.6 Legitimate Explanation Only If Drug Used for Intended Medical Purpose.

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.

8.9.7 MRO May Have to Inform Employer Even If Legitimate Use.

Even if the MRO finds that there is a legitimate medical explanation under paragraph 8.9.5 and verifies a test negative, the MRO may have a responsibility to raise fitness-for-duty considerations with the employer (see Section 17.3).

8.10 The MRO Must Proceed as Follows When a Laboratory Confirmed Positive Opiate Result Is Received. (§40.l39)

8.10.1 Positive if 6-AM.

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

8.10.2 Positive if Morphine or Codeine at 15,000 ng/mL or above.

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 8.9). 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.

8.10.3 Other Opiate Results.

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).

8.10.3.1 A MRO is responsible to use his or her best professional and ethical judgment and discretion to determine whether there is clinical evidence of unauthorized use of opiates. Examples of information that may be considered in making this judgment include, but are not limited to, the following:

8.10.3.1.1 Recent needle tracks;

8.10.3.1.2 Behavioral and psychological signs of acute opiate intoxication or withdrawal;

8.10.3.1.3 Clinical history of unauthorized use recent enough to have produced the laboratory test results;

8.10.3.1.4 Use of a medication from a foreign country. See 8.9.5 for guidance on how to make this determination.

8.10.3.2 In order to establish the clinical evidence referenced in paragraphs 8.10.3.1.1 and 8.10.3.1.2, personal observation of the employee is essential.

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

8.10.3.2.2 No face-to-face examination is needed in establishing the clinical evidence referenced in paragraph 8.10.3.1.3 or 8.10.3.1.4.

8.10.3.3 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 does not have grounds for verifying the test positive. The admission must be for the substance that was found).

8.10.3.4 The MRO, has the burden of establishing that there is clinical evidence of unauthorized use of opiates referenced in this paragraph 8.10.3. 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.

8.11 The MRO Must Do the Following as the MRO Makes the Determinations Needed for a Verification Decision. (§40.141)

8.11.1 The MRO Must Conduct a Medical Interview. The MRO must review the employee medical history and any other relevant biomedical factors presented to the

MRO by the employee. The MRO may direct the employee to undergo further medical evaluation by the MRO or another physician.

8.11.2 Verify Authenticity of Employee Medical Records. 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.

8.12 Basis upon Which the MRO Verifies Test Results Involving Adulteration or Substitution. (§40.145)

8.12.1 Adulterated or Substituted Report. When a MRO receives a laboratory report that a specimen is adulterated or substituted, the MRO must treat that report in the same way the MRO treats the laboratory report of a confirmed positive test for a drug or drug metabolite.

8.12.1.1 If the laboratory has reported the creatinine concentration for a substituted specimen as equal to or more than 2 mg/dL but less than 5 mg/dL, the MRO must report the specimen to the DER as being dilute, as provided in Section 8.16. Notwithstanding any other provision of this document, the MRO must also instruct the DER that a second collection under direct observation must take place immediately.

8.12.1.2 If the laboratory has reported the creatinine concentration for a substituted specimen as less than 2 mg/dL and the specific gravity is less than or equal to 1.0010 or greater than or equal to 1.200 on both the initial and confirmatory creatinine tests and on both the initial and confirmatory specific gravity tests on two separate aliquots, the MRO must follow the procedures in 8.12.2 and 8.12.8.

8.12.2 Verification Procedure. The MRO must follow the same procedures used for verification of a confirmed positive test for a drug or drug metabolite (see Sections 8.5, 8.8, 8.11, and 8.14), except as otherwise provided in this section.

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

8.12.4 Give Employee a Chance to Explain. 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.

8.12.5 Employee Has the Burden of Proof. The employee has the burden of proof that there is a legitimate medical explanation.

8.12.5.1 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.

8.12.5.2 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 concentration criterion of less than 2 mg/dL and the specific gravity criteria of less than or equal to 1.0010 or greater than or equal to 1.0200.

8.12.5.3 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.

8.12.6 MRO Not Responsible for Arranging, Conducting, or Paying for Studies, Etc. The MRO or the employer is not responsible for arranging, conducting, or paying for any studies, examinations or analyses to determine whether a legitimate medical explanation exists.

8.12.7 MRO's Judgment. The MRO must exercise his or her best professional judgment in deciding whether the employee has established a legitimate medical explanation.

8.12.7.1 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 test must be reported to the DER as a verified refusal to test because of adulteration or substitution, as applicable.

8.12.7.2 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 8.12.5.3, 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' explanation. (The MRO may perform this evaluation if the MRO has appropriate expertise.)

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

8.12.7.2.2 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:

8.12.7.2.2.1 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;

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

8.12.7.2.2.3 That the referral physician must agree to follow the requirements of paragraphs 8.12.7.3 through 8.12.7.4 of this section; and

8.12.7.2.2.4 That the referral physician must provide the MRO with a signed statement of his or her recommendations.

8.12.7.3 The referral physician must evaluate the employee and consider any evidence the employee presents concerning the employee's medical explanation. The physician 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.

8.12.7.4 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. The MRO must seriously consider and assess the referral physician's recommendation in deciding whether there is a legitimate medical explanation.

8.12.7.5 If the MRO determines that there is a legitimate medical explanation, he or she 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).

8.12.7.6 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.

8.12.8 Examples of Valid Evidence.

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.

8.12.8.1 Medically valid evidence demonstrating that the employee is capable of physiologically producing urine meeting the creatinine and specific gravity criteria of paragraph 7.7.2.

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

8.12.8.1.2 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 paragraph 7.7.2.

8.12.8.2 Information from a medical evaluation under paragraph 8.12.7 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 paragraph 7.7.2.

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

8.12.8.2.2 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 paragraph 7.7.2.

8.13 Changes of a Verified Positive Drug Test Result or Refusal to Test by the MRO. (§40.149)

8.13.1 When a Test Result May Be Changed.

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

8.13.1.1 When the MRO has reopened a verification that was done without an interview with an employee (see paragraph 8.7.3).

8.13.1.2 If the MRO receives information, not available to the MRO 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 to the MRO. 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.

8.13.1.3 If, within 60 days of the original verification decision:

8.13.1.3.1 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) or metabolite(s) in the employee's specimen; or

8.13.1.3.2 The MRO receives credible new or additional evidence that a legitimate medical explanation for an adulterated or substituted result exists.

Example: If the employee's physician provides to the MRO 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) or metabolite(s) in the employee's specimen.

8.13.1.4 If the MRO receives the information in paragraph 8.13.1.3 after the 60-day period, the MRO must consult with ODAPC prior to changing the result.

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

8.13.2 DER Must be Notified.

If the MRO changes the result, the MRO must immediately notify the DER in writing, as provided in Sections 8.19 and 8.20.

8.13.3 Only MRO Can Change Test Results.

The MRO is the only person permitted to change a verified test result.

8.14 The MRO is Prohibited from Doing the Following as Part of the Verification Process. (§40.l5l)

8.14.1 Consider Other Tests.

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 49 CFR Part 40. For example, if an employee tells the MRO he went to his own physician, provided a urine specimen, sent it to a laboratory, and received a negative test result or a DNA test result questioning the identity of his DOT specimen, the MRO is required to ignore this test result.

8.14.2 Consider Information Outside the CCF.

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

8.14.3 Consider Whether the Employee Should Have Been Selected for Testing.

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

8.14.4 Consider Illegitimate Explanations.

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

8.14.5 Consider Prescription for Schedule I Controlled Substances.

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).

8.14.6 Consider Certain Claims.

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.

8.14.7 Legitimate Reason for PCP or 6-AM.

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.

8.14.8 Consider Physiological Reason for Soap, Bleach, Etc. in Specimen.

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.

8.14.9 Consider Explanation for No Detectable Creatinine.

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.

8.15 The MRO shall Notify Employees of Their Right to a Test of the Split Specimen as Follows. (§40.153)

8.15.1 Notify Employee of Right to Test Split Specimen.

When the MRO has verified a drug test as positive for a drug or drug metabolite, or as a refusal to test because of adulteration or substitution, the MRO 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.

8.15.2 Time for Employee to Decide to Test Split Specimen.

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.

8.15.3 Tell Employee How to Contact MRO.

The MRO must tell the employee how to contact him or her 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 office to answer the phone).

8.15.4 Explain Payment for the Test.

The MRO must tell the employee that if he or she makes this request within 72 hours, the employer must ensure that the test takes place, and that the employee is not required to pay for the test from his or her own funds before the test takes place. The MRO must also tell the employee that the employer may seek reimbursement for the cost of the test (see Section 9.2).

8.15.5 No Additional Tests Authorized.

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

8.16 Procedure When a Negative or Positive Test Result Is Also Dilute. (§40.155)

8.16.1 MRO Reporting. 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.

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

8.16.3 MRO Must Have Copies 1 and 2 of CCF Before Reporting. 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.

8.16.4 Explain to DER What Is Required. When the MRO reports a dilute specimen to the DER, the MRO must explain to the DER the employer's obligations and choices under **Section** 10.4, to include the requirement for an immediate recollection under direct observation if the creatinine concentration of a negative-dilute specimen was greater than or equal to 2 mg/dL but less than or equal to 5 mg/dL.

8.17 Procedures When a Drug Test Result Is Invalid. (§40.159)

8.17.1 MRO Duties. When the laboratory reports that the test result is an invalid result the MRO must do the following:

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

8.17.1.2 Contact the employee and inform the employee that the specimen was invalid or contained an unexplained interfering substance. In contacting the employee, use the procedures set forth in Section 8.6.

8.17.1.3 After explaining the limits of disclosure (see paragraphs 8.8.4 and 17.3), the MRO should inquire as to medications the employee may have taken that may interfere with some immunoassay tests.

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

8.17.1.4.1 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.

8.17.1.4.2 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).

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

8.17.1.5.1 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.

8.17.1.5.2 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.

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

8.17.2 MRO Must Have Copies 1 and 2 of CCF Before Reporting. 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.

8.17.3 MRO Documentation of Employee Admissions. 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 told him or her. The MRO must then report a refusal to test in accordance with **Section** 8.19.

8.18 When the Laboratory Reports That the Specimen Is Rejected for Testing (E.g., Because of a Fatal or Uncorrected Flaw), the MRO Must Do the Following. (§40.161)

8.18.1 Mark CCF. 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.

8.18.2 Report to DER. 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).

8.18.3 MRO Must Have Copies 1 and 2 of CCF Before Reporting.

The MRO may only report a test cancelled because of a rejected 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.

8.19 Procedure for Reporting Drug Test Results. (§40.l63)

8.19.1 Report Must Be in Writing.

It is the MRO's responsibility to report the drug test results to the employer in writing.

8.19.1.1 The MRO or a staff member may rubber stamp a report of negative results. If a MRO uses a rubber stamp, the MRO or the MRO's staff must also initial the stamp to identify who affixed the stamp to the report.

8.19.1.2 The MRO must sign reports of all other results.

8.19.2 Copy 2 Must Be Used to Report Results.

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

8.19.3 Alternate Methods of Reporting Results.

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:

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

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

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

8.19.3.4 Date of the collection;

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

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

8.19.3.7 For cancelled tests, the reason for cancellation; and

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

8.19.4 Document Retention.

The MRO must retain a signed or stamped and dated copy of Copy 2 of the CCF in the MRO's 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.

8.19.5 Copy 1 Can Not Be Used to Report Results.

Copy 1 of the CCF must not be used to report drug test results.

8.19.6 No Quantitative Results to Be Reported.

Quantitative values must not be provided to the DER or C/TPA for drug or validity test results. However, the MRO must provide the test information in his or her possession to a SAP who consults with the MRO (see 16.7.7).

8.20 The MRO Transmits Reports of Drug Test Results as Follows. (§40.l65)

8.20.1 Report to DER.

The MRO must report all drug test results to the DER, except in the circumstances provided for in Section 18.3.

8.20.2 Report to C/TPA.

If the employer elects to receive reports of results through a C/TPA, acting as an intermediary as provided in Section 18.3, the MRO must report the results through the designated C/TPA.

8.21 The MRO or C/TPA Who Transmits Drug Test Results to the Employer Must Comply with the Following Requirements. (§40.167)

8.21.1 The Results Must Be Reported in a Confidential Manner.

8.21.2 Time for Reporting Certain Results.

All verified positive test results, results requiring an immediate collection under direct observation, adulterated or substituted specimen results, and other refusals to test must be transmitted to the DER on the same day the MRO verifies the result or the next business day.

8.21.2.1 Direct telephone contact with the DER is the preferred method of immediate reporting. Follow up the phone call with appropriate documentation (see Section 8.19).

8.21.2.2 The MRO or C/TPA is responsible for identifying him or herself to the DER, and the DER must have a means to confirm the identification.

8.21.2.3 The MRO's report transmitted to the employer must contain all of the information required by Section 8.19.

8.21.3 MRO's Written Report.

The MRO's written report of verified tests must be transmitted to the DER so that the DER receives them within two days of verification by the MRO.

8.21.4 Security Must Be Insured. In transmitting test results, the MRO or the C/TPA and the employer must ensure the security of the transmission and limit access to any transmission, storage, or retrieval systems.

8.22 Medical Review Officer Record Retention for Controlled Substances. (§382.409)

8.22.1 5 Year Retention. A MRO or third party administrator shall maintain all dated records and notifications, identified by individual, for a minimum of five years for verified positive controlled substances test results.

8.22.2 1 Year Retention. A MRO or third party administrator shall maintain all dated records and notifications, identified by individual, for a minimum of one year for negative and cancelled controlled substances test results.

8.22.3 No Results Released Without the Specific Written Consent of Employee. No person may obtain the individual controlled substances test results retained by a MRO or third party administrator, and no MRO or third party administrator shall release the individual controlled substances test results of any driver to any person, without first obtaining a specific, written authorization from the tested driver. Nothing in this

paragraph shall prohibit a MRO from releasing, to the employer or to officials of the Secretary of Transportation, any DOT agency, or any State or local officials with regulatory authority over the controlled substances testing program under this part, the information delineated in 8.21.1.

8.23 Additional Information. (§40.169)

Additional information on the role of the MRO is in the following sections:

1.3 - definition.
5.4 - 5.5 - correction of form and kit errors.
6.4 - role in direct observation and other atypical test situations.
7.2 - laboratory handling of fatal and correctable flaws.
7.9 - laboratory handling of test results and quantitative values.
7.10 - authorization of longer laboratory retention of specimens.
7.11 - relationship with laboratories; avoidance of conflicts of interest.
7.13 - notification of discrepancies in blind specimen results.
9.1 - request for test of split specimen.
9.9 - action concerning split specimen test results.
10.2 - role in "shy bladder" situations.
10.3 - role in canceling tests.
10.5 - 10.7 - documenting errors in tests.
17.3 - confidentiality and release of information.
18.4 - transfer of records.
18.7 - relationships with service agents

9. Split Specimen Tests.

9.1 Employee Request for a Test of a Split Specimen. (§40.171)

9.1.1 When Request Must Be Made. When the MRO has notified an employee that the employee has a verified positive drug test or refusal to test because of adulteration or substitution, the employee 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.

9.1.2 Late Requests.

9.1.2.1 If an 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 the employee from making a timely request.

9.1.2.2 If the MRO concludes from the employee's information that there was a legitimate reason for the employee's failure to contact the MRO 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.

9.1.3 When MRO Must Request the Lab to Test the Split Specimen. When the employee makes a timely request for a test of the split specimen under paragraphs 9.1.1 and 9.1.2, 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.

9.2 Who Is Responsible for Paying for the Test of a Split Specimen. (§40.173)

9.2.1 Employer Responsible for Having the Test Performed. The employer 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 Sections 9.3 - 9.8 in a timely manner, once the employee has made a timely request for a test of the split specimen.

9.2.2 Employer Can Not Condition Compliance on Employee Direct Payment. The employer 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 the employer for the costs of testing. For example, if the employer 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 employer must ensure that the test takes place in a timely manner, even though this means that the employer pays for it.

9.2.3 Employer May Seek Reimbursement from Employee. The employer may seek payment or reimbursement of all or part of the cost of the split specimen from the employee (e.g., through written Employer policy or a collective bargaining agreement). 49 CFR Part 40 takes no position on who ultimately pays the cost of the test, so long as the employer ensures that the testing is conducted as required and the results released appropriately.

9.3 Steps the First Laboratory Takes with a Split Specimen. (§40.175)

9.3.1 Check If Split Specimen Is Available. The laboratory at which the primary and split specimen first arrives must check to see whether the split specimen is available for testing.

9.3.2 Procedure If Split Specimen Is Not Available. If the split specimen is unavailable or appears insufficient, the first laboratory must then do the following:

9.3.2.1 Continue the testing process for the primary specimen as normal. Report the results for the primary specimen without providing the MRO information regarding the unavailable split specimen.

9.3.2.2 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 as possible about the cause of the unavailability.

9.3.3 First Lab Not Authorized to Open Split Specimen.

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 paragraph 7.2.7).

9.3.4 Procedure for Sending Split Specimen to Second Lab.

When the laboratory receives written notice from the MRO instructing that the split specimen be sent to another HHS-certified laboratory, the first laboratory must forward the following items to the second laboratory:

9.3.4.1 The split specimen in its original specimen bottle, with the seal intact;

9.3.4.2 A copy of the MRO's written request; and

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

9.3.5 No Information Identifying Employee to Be Sent to Second Lab.

The first 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.

9.3.6 Any HHS Certified Lab May Be Used to Test Split Specimen.

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

9.4 Second Laboratory Procedure for Testing the Split Specimen to Reconfirm the Presence of a Drug or Drug Metabolite. (§40.l77)

9.4.1 Second Lab Must Test for Substance Detected by First Lab.

The laboratory testing the split specimen must test the split specimen for the drug(s) or drug metabolite(s) detected in the primary specimen.

9.4.2 Test Must Ignore Cut Off Concentrations.

This test must be conducted without regard to the cutoff concentrations of paragraph 7.4.1.

9.4.3 Procedure If Failure to Reconfirm.

If the test fails to reconfirm the presence of the drug(s) or drug metabolite(s) that were reported positive in the primary specimen, the second laboratory must conduct validity tests in an attempt to determine the reason for being unable to reconfirm the presence of the drug(s) or drug metabolite(s). The same validity tests should be conducted as would be conducted on a primary specimen set forth in Section 7.6.

9.4.4 Specimen May Be Sent to Third Lab If Second Lab Fails to Reconfirm.

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 second laboratory may transmit the specimen or an aliquot of it to another HHS-certified laboratory that will conduct another reconfirmation test.

9.5 Specimen Must Be Tested for Adulterant Found. (§40.l79)

The laboratory testing the split specimen must test the split specimen for the adulterant detected in the primary specimen, using the criteria of Section 7.8 just as for a primary specimen. The result of the primary specimen is reconfirmed if the split specimen meets these criteria.

9.6 Definition of "Reconfirmed." (§40.181)

The laboratory testing the split specimen must test the split specimen using the criteria of paragraph 7.7.2, as would be done for a primary specimen. The result of the primary specimen is reconfirmed if the split specimen meets these criteria.

9.7 Information Reported by the Laboratories to MROs Regarding Split Specimen Results. (§40.183)

9.7.1 Mark CCF.

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.

9.7.2 Additional Information Required If "Fail to Reconfirm."

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

9.7.2.1 "Drug(s) or Drug Metabolite(s) Not Detected."

9.7.2.2 "Adulterant not found within criteria."

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

9.7.2.4 "Specimen not available for testing."

9.7.3 Sign CCF.

The laboratory certifying scientist enters his or her name, signs, and dates the CCF.

9.8 Laboratory Report of Split Specimen Results. (§40.185)

9.8.1 Lab Reports to MRO Only. 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).

9.8.2 Method of Transmission. 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.

9.8.3 When Report Must Be Sent. 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.

9.9 The MRO Must Take the Following Actions When a Laboratory Reports the Following Results of Split Specimen Tests. (§40.187)

9.9.1 Reconfirmed.

9.9.1.1 In the case of a reconfirmed positive test for a drug or drug metabolite, report the reconfirmation to the DER and the employee.

9.9.1.2 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.

9.9.1.3 In the case of a reconfirmed substituted result, in which the

creatinine concentration for the primary specimen was less than 2 mg/dL and the creatinine concentration of the split specimen is between 2 and 5 mg/dL, inclusive, report the result to the Employer as "dilute" and instruct the Employer to conduct an immediate recollection under direct observation.

9.9.2 Failed to Reconfirm: Drug(s) or Drug Metabolite(s) Not Detected.

9.9.2.1 Report to the DER and the employee that both tests must be cancelled.

9.9.2.2 Using the format in Appendix D to 49 CFR Part 40, inform ODAPC of the failure to reconfirm.

9.9.3 Failed to Reconfirm: Adulteration or Substitution (as appropriate) Criteria Not Met.

9.9.3.1 Report to the DER and the employee that both tests must be cancelled.

9.9.3.2 Using the format in Appendix D to 49 CFR Part 40, inform ODAPC of the failure to reconfirm.

9.9.4 Failed to Reconfirm: Specimen Not Available for Testing.

9.9.4.1 Report to the DER and the employee that both tests must be cancelled and the reason for cancellation.

9.9.4.2 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.

9.9.4.3 Using the format in Appendix D to 49 CFR Part 40, notify ODAPC of the failure to reconfirm.

9.9.5 MRO Signs Form. The MRO enters his or her name, signs and dates (Step 7) of Copy 2 of the CCF.

9.9.6 Disposition of Form. Send a legible copy of Copy 2 of the CCF (or a signed and dated letter, see Section 8.19 to the employer and keep a copy for the MRO's records. Transmit the document as provided in Section 8.21.

9.10 Additional Information. (§40.189)

More information concerning split specimens can be found in the following sections:

3.1 - definition.
6.3 - quantity of split specimen.
6.4 - directly observed test when split specimen is unavailable.
6.6-6.7 - collection process for split specimens.
7.2 - laboratory accessioning of split specimens.
7.10 - laboratory retention of split specimens
7.12 - blind split specimens.

8.15 - MRO notice to employees on tests of split specimen.
10.2 and 10.6 - MRO actions on insufficient or unavailable split specimens.
Appendix D - Report format for split specimen failure to reconfirm.

10. Problems in Drug Tests.

10.1 Definition of Refusal to Test. (§40.191)

10.1.1 Refusal to Test. An employee has refused to take a drug test if:

10.1.1.1 The employee fails to appear for any test within a reasonable time, as determined by the employer, after being directed to do so by the employer. This includes the failure of an employee (including an owner-operator) to appear for a test when called by C/TPA (see paragraph 6.1.1);

10.1.1.2 The employee fails to remain at the testing site until the testing process is complete;

10.1.1.3 The employee fails to provide a urine specimen for any drug test required by 49 CFR Part 40 or DOT agency regulations;

10.1.1.4 In the case of a directly observed or monitored collection in a drug test, the employee fails to permit the observation or monitoring of the provision of a specimen (see paragraph 6.4.12 and 6.5.7);

10.1.1.5 The employee 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 paragraph l0.2.4.2);

10.1.1.6 The employee fails or declines to take an additional drug test the employer or collector has directed the employee to take;

10.1.1.7 The employee 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 as part of the "shy bladder" procedures of 49 CFR Part 40 (see paragraph 10.2.4). In the case of a pre-employment drug test, the employee is deemed to have refused to test on this basis only if the pre-employment test is conducted following a contingent offer of employment. If there is no contingent offer of employment, the MRO will cancel the test; or

10.1.1.8 The employee fails to cooperate with any part of the testing process (e.g., refuse to empty pockets when so directed by the collector, behaves in a confrontational way that disrupts the collection process).

10.1.2 Verified Adulterated or Substituted Result.

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

10.1.3 Refusal to Take Test.

If an employee refuses to take a drug test, the employee incurs the consequences specified under DOT agency regulations for a violation of those DOT agency regulations.

10.1.4 Procedure When Employee Refuses to Participate.

As the collector or MRO, when an employee refuses to participate in the part of the testing process in which the collector or the MRO, as the case may be is involved, that portion of the testing process must be terminated, the collector or MRO must document the refusal on the CCF (or in a separate document attached to the form), immediately notify the DER by any means (e.g., telephone or secure fax machine) that ensures that the refusal notification is immediately received. A referral physician (e.g., physician evaluating a "shy bladder" condition or a claim of a legitimate medical explanation in a validity testing situation), must notify the MRO, who in turn will notify the DER.

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

10.1.4.2 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.

10.1.5 Refusal to Take Non-DOT Test Not Refusal to Test.

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.

10.2 Insufficient Amount of Urine for a Drug Test. (§40.193)

10.2.1 Procedure.

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).

10.2.2 The Collector Must Do the Following:

10.2.2.1 Discard the insufficient specimen, except where the insufficient specimen was out of temperature range or showed evidence of adulteration or tampering (see paragraphs 6.3.2 and 6.3.3).

10.2.2.2 Urge the employee to drink up to 40 ounces of fluid, distributed reasonably through a period of up to three hours, or until the individual has provided a sufficient urine specimen, whichever occurs first. It is not a refusal to test if the employee declines to drink.

10.2.2.3 If the employee refuses to make the attempt to provide a new urine specimen, the collector 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.

10.2.2.4 If the employee has not provided a sufficient specimen within three hours of the first unsuccessful attempt to provide the specimen, the collection must be discontinued, note the fact on the "Remarks" line of the CCF (Step 2), and immediately notify the DER.

10.2.2.5 Copy 2 of the CCF must be sent to the MRO and Copy 4 must be sent to the DER. These copies must be sent or faxed to the MRO and DER within 24 hours or the next business day.

10.2.3 Employee Evaluation by a Physician.

When the collector informs the DER that the employee has not provided a sufficient amount of urine (see paragraph 10.2.2.4), 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.)

10.2.3.1 If another physician will perform the evaluation the MRO must provide the other physician with the following information and instructions:

10.2.3.1.1 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;

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

10.2.3.1.3 That the referral physician must agree to follow the requirements of paragraphs 10.2.4 through 10.2.5.

10.2.4 Physician's Determination.

The referral physician conducting this evaluation must recommend that the MRO make one of the following determinations:

10.2.4.1 A medical condition has, or with a high degree of probability could have, precluded the employee from providing a sufficient amount of urine. As the MRO, if MRO accepts this recommendation, the MRO must:

10.2.4.1.1 Check "Test Cancelled" (Step 6) on the CCF; and

10.2.4.1.2 Sign and date the CCF.

10.2.4.2 There is not an adequate basis for determining that a medical condition has, or with a high degree of probability could have, precluded the employee from providing a sufficient amount of urine. If the MRO accepts this recommendation, the MRO must:

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

10.2.4.2.2 Sign and date the CCF.

10.2.5 Definition of "Medical Condition."

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.

10.2.6 Physician's Written Report to MRO.

The referral physician making the evaluation, after completing his or her evaluation, must provide a written statement of recommendations and the basis for them to the MRO. The referral physician must not include in this statement detailed information

on the employee's medical condition beyond what is necessary to explain his or her conclusion.

10.2.7 Pre-employment - Physician's Report.

If the referral physician making this evaluation in the case of a pre-employment test determines 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, this determination and the reasons for it must be set forth in the written statement to the MRO. The MRO, upon receiving such a report must follow the requirements of Section 10.3, where applicable.

10.2.8 MRO Consideration of Physician's Report.

The MRO must seriously consider and assess the referral physician's recommendations in making a 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's determination must be reported to the DER in writing as soon as it is made.

10.2.9 No Further Action If Test Cancelled.

When the employer receives a report from the MRO indicating that a test is cancelled as provided in paragraph 10.2.4.1, the employer must take no further action with respect to the employee. The employee remains in the random testing pool.

10.3 Procedure When an Individual Is Unable to Provide a Sufficient Amount of Urine for a Pre-employment or Return-to-Duty Test Because of a Permanent or Long-term Medical Condition. (§40.l95)

10.3.1 Procedure.

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:

10.3.1.1 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 paragraph 10.2.4.

10.3.1.2 If the MRO does not personally conduct the medical evaluation, the MRO must ensure that one is conducted by a licensed physician acceptable to the MRO.

10.3.1.3 For purposes of this section, the MRO or the physician conducting the evaluation may conduct an alternative test (e.g., blood) as part of the medically appropriate procedures in determining clinical evidence of drug use.

10.3.2 Result If No Clinical Evidence of Drug Use.

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 paragraph 10.2.4 and any further medical examination. This report must state the MRO's 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.

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

10.3.2.2 Sign and date the CCF.

10.3.3 Result If Clinical Evidence of Drug Use.

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 paragraph 10.2.4 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).

10.3.4 Definition of "Permanent or Long-term Medical Conditions." 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.

10.3.4.1 Examples would include destruction (any cause) of the glomerular filtration system leading to renal failure; unrepaired traumatic disruption of the urinary tract; or a severe psychiatric disorder focused on genito-urinary matters.

10.3.4.2 Acute or temporary medical conditions, such as cystitis, urethritis or prostatitis, though they might interfere with collection for a limited period of time, cannot receive the same exceptional consideration as the permanent or long-term conditions discussed in paragraph 10.3.4.1.

10.4 Procedure When an Employer Receives a Report of a Dilute Specimen. (§40.197)

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

10.4.2 Dilute Negative Test.

10.4.2.1 If the MRO informs the employer that a negative drug test was dilute, the employer 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 paragraphs 6.4.2 and 6.4.3).

10.4.2.2 If the MRO informs the employer that a negative test was dilute, the employer must:

10.4.2.2.1 If the MRO directs the employer to conduct a recollection under direct supervision (for example, because the creatinine concentration of the specimen was equal to or greater

than 2mg/dL, but less than or equal to 5 mg/dL), the employer must do so immediately.

10.4.2.2.2 Otherwise (if the creatinine concentration of the dilute specimen is greater than 5 mg/dL), the employer may, but is not required to, direct the employee to take another test immediately.

10.4.2.2.2.1 Such recollections must not be collected under direct observation, unless there is another basis for use of direct observation

10.4.3 Employer Must Treat All Employees the Same. The employer must treat all employees the same for this purpose. For example, the employer must not retest some employees and not others. The employer 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 employer must inform its employees in advance of its decisions on these matters.

10.4.4 Employee to Receive Minimum Notice of New Test. If the employer directs the employee to take another test, the employer must ensure that the employee is given the minimum possible advance notice that he or she must go to the collection site.

10.4.5 New Test Becomes Test of Record. If the employer 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 employer relies for purposes of 49 CFR Part 40.

10.4.6 Employer Can Not Require Third Test. If the employer requires employees to take another test, and the second test is also negative and dilute, the employer is not permitted to make the employee take a third test because the second test was dilute. Provided, however, that if the MRO directs the employer to conduct a recollection under direct observation under this section, the employer must immediately do so.

10.4.7 Employee Refusal to take a Test Is Refusal to Test. If the employer directs the employee to take another test and the employee declines to do so, the employee has refused the test for purpose of 49 CFR Part 40 and DOT agency regulations.

10.5 Problems Always Causing a Drug Test to Be Cancelled. (§40.199)

10.5.1 Fatal Flaw. When the laboratory discovers a "fatal flaw" during its processing of incoming specimens (see Section 7.2), 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.

10.5.2 The Following Are "Fatal Flaws:"

10.5.2.1 There is no printed collector's name and no collector's signature;

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

10.5.2.3 The specimen bottle seal is broken or shows evidence of tampering (and a split specimen cannot be re-designated, see Section 7.2); and

10.5.2.4 Because of leakage or other causes, there is an insufficient

amount of urine in the primary specimen bottle for analysis and the specimens cannot be re-designated (see paragraph 7.2.7).

10.5.3 Reporting. Report the result as provided in Section 8.21.

10.6 Tests That Must Be Cancelled. (§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 10.6.1 through 10.6.6.

10.6.1 Invalid Result. The laboratory reports an "Invalid Result." The applicable procedures in **Section** 8.17 (recollection under direct observation may be required) must be followed.

10.6.2 Rejected for Testing. The laboratory reports the result as "Rejected for Testing." The applicable procedures in Section 8.18 (a recollection may be required) must be followed.

10.6.3 Primary Specimen Positive, Split Specimen "Failure to Reconfirm: Drug(s) or Drug Metabolite(s) Not Detected."

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." Follow applicable procedures in paragraph 9.9.2 (no recollection is required in this case).

10.6.4 Primary Specimen Adulterated or Substituted, Split Specimen "Adulterant Not Found Within Criteria," or " Specimen Not Consistent with Substitution."

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 applicable procedures in paragraph 9.9.3 (no recollection is required in this case) must be followed.

10.6.5 Primary Specimen Positive, Adulterated, or Substituted, Split Specimen Unavailable.

The laboratory's test of the primary specimen is positive, adulterated, or substituted and the split specimen is unavailable for testing. The applicable procedures in paragraph 9.9.4 (recollection under direct observation is required in this case) must be followed.

10.6.6 Acceptable Medical Explanation.

The examining physician has determined that there is an acceptable medical explanation of the employee's failure to provide a sufficient amount of urine. Follow applicable procedures in paragraph 10.2.4.1 (no recollection is required in this case).

10.7 Problems That Cause a Drug Test to Be Canceled Unless They Are Corrected. (§40.203)

10.7.1 Correctable Flaw.

When a laboratory discovers a "correctable flaw" during its processing of incoming specimens (see Section 7.2), 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).

10.7.2 The Following Are "Correctable Flaws."

Laboratories must attempt to correct the following:

10.7.2.1 The collector's signature is omitted on the certification statement on the CCF.

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

10.7.3 MRO Discovery of Correctable Flaws.

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

10.7.4 The Following Are Correctable Flaws.

The MRO must attempt to correct the following:

10.7.4.1 The employee's signature is omitted from the certification statement, unless the employee's failure or refusal to sign is noted on the "Remarks" line of the CCF.

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

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

10.8 Correcting Drug Test Problems. (§40.205)

10.8.1 Collector's Responsibility.

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

10.8.1.1 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.

10.8.1.2 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.

10.8.2 Party Discovering Problem Must Try to Correct It.

If a collector, laboratory, MRO, employer, or other person implementing these drug testing regulations becomes aware of a problem that can be corrected (see Section 10.7), but which has not already been corrected under paragraph 10.8.1 the party discovering the problem must take all practicable action to correct the problem so that the test is not cancelled.

10.8.2.1 If the problem resulted from the omission of required information, the person responsible for providing that information, must supply in writing the missing information and a statement that it is true and accurate. For example, suppose a collector forgets 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 or her attention, supply a signed statement that the employee failed or refused to sign the certification and that the statement is true and accurate. This information must be supplied on the same business day on which notice is received of the problem, transmitting it by fax or courier.

10.8.2.2 If the problem is the use of a non-Federal form, the person responsible for the use of the incorrect form must provide a signed statement that the incorrect form contains all the information needed for a valid DOT drug test, that the incorrect form was used inadvertently or as the only means of conducting a test, in circumstances beyond the control of the person using the form. The statement must also list the steps taken to prevent future use of non-Federal forms for DOT tests. For this flaw to have been corrected, the test of the specimen must have occurred at a HHS-certified laboratory where it was tested using the testing protocol in 49 CFR Part 40. This information must be supplied on the same business day on which notice is received of the problem, transmitting it by fax or courier.

10.8.2.3 The written documentation of a correction must be maintained with the CCF.

10.8.2.4 The CCF must be marked in such a way (e.g., stamp noting correction) as to make it obvious on the face of the CCF that the flaw was corrected.

10.8.3 If No Correction, Test Cancelled.

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

10.9 The Following Is the Effect of a Cancelled Drug Test. (§40.207)

10.9.1 A Cancelled Drug Test Is Neither Positive Nor Negative.

10.9.1.1 An employer 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).

10.9.1.2 An employer 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).

10.9.1.3 An employer must not direct a recollection for an employee because a test has been cancelled, except in the situations cited in paragraph 10.9.1.2 or other provisions of 49 CFR Part 40 that require another test to be conducted (e.g., paragraphs 8.17.1.5 and 9.9.1).

10.9.2 A Cancelled Test Does Not Count Toward Compliance with DOT Requirements

(e.g., being applied toward the number of tests needed to meet the employer's

minimum random testing rate).

10.9.3 A Cancelled DOT Test Does Not Provide a Valid Basis for an Employer to Conduct a Non-DOT Test

(i.e., a test under Employer authority).

10.10 The Effect of Procedural Problems That Are Not Sufficient to Cancel a Drug Test. (§40.209)

10.10.1 Errors Must Be Documented.

A collector, laboratory, MRO, employer or other person administering the drug testing process must document any errors in the testing process of which the party 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 10.10.2.

10.10.2 Errors Which Are Not Grounds for Canceling a Test.

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:

10.10.2.1 A minor administrative mistake (e.g., the omission of the employee's middle initial, a transposition of numbers in the employee's social security number);

10.10.2.2 An error that does not affect employee protections under 49 CFR Part 40 (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);

10.10.2.3 The collection of a specimen by a collector who is required to have been trained (see Section 4.2), but who has not met this requirement;

10.10.2.4 A delay in the collection process (see paragraph 6.1.1);

10.10.2.5 Verification of a test result by an MRO who has the basic credentials to be qualified as an MRO (see paragraphs 8.1.1 through 8.1.2) but who has not met training and/or documentation requirements (see paragraphs 8.1.3 through 8.1.5);

10.10.2.6 The failure to directly observe or monitor a collection that the rule requires or permits to be directly observed or monitored, or the unauthorized use of direct observation or monitoring for a collection;

10.10.2.7 The fact that a test was conducted in a facility that does not meet the requirements of Section 5.1;

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

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

or

10.10.2.10 Claims that the employee was improperly selected for testing.

10.10.3 Sanctions for Errors.

These types of errors, even though not sufficient to cancel a drug test result, may subject the employer to enforcement action under DOT agency regulations.

11. Alcohol Testing Personnel.

11.1 Who Conducts DOT Alcohol Tests. (§40.211)

11.1.1 STTs and BATs.

Screening test technicians (STTs) and breath alcohol technicians (BATs) meeting their respective requirements of this subpart are the only people authorized to conduct DOT alcohol tests.

11.1.2 Tests Which STTs and BATs May Conduct.

An STT can conduct only alcohol screening tests, but a BAT can conduct alcohol screening and confirmation tests.

11.1.3 When an Immediate Supervisor Can Act as a BAT or STT.

A BAT- or STT-qualified immediate supervisor of a particular employee may not act as the STT or BAT when that employee is tested, unless no other STT or BAT is available and DOT agency regulations do not prohibit the immediate supervisor from doing so.

11.2 A BAT or STT in the DOT Alcohol Testing Program Must Meet Each of the Following Requirements: (§ 40.213)

11.2.1 Qualification.

The person must be knowledgeable about the alcohol testing procedures in 49 CFR Part 40 and the current DOT guidance. These documents and information are available from ODAPC (Department of Transportation, 400 7th Street, SW., Room 10403, Washington DC, 20590, 202-366-3784, or on the ODAPC web site, http://www.dot.gov/ost/dapc)).

11.2.2 Qualification Training.

The following qualification training is required:

11.2.2.1 Qualification training must be in accordance with the DOT Model BAT or STT Course, as applicable. The DOT Model Courses are available from ODAPC (Department of Transportation, 400 7th Street, SW., Room 10403, Washington DC, 20590,202-366-3784, or on the ODAPC web site, http://www.dot.gov/ost/dapc). The training can also be provided using a course of instruction equivalent to the DOT Model Courses. On request, ODAPC will review BAT and STT instruction courses for equivalency.

11.2.2.2 Qualification training must include training to proficiency in using the alcohol testing procedures of 49 CFR Part 40 and in the operation of the particular alcohol testing device(s) (i.e., the ASD(s) or EBT(s)) the person will be using.

11.2.2.3 The training must emphasize that the technician is responsible for maintaining the integrity of the testing process, ensuring the privacy of employees being tested, and avoiding conduct or statements that could be

viewed as offensive or inappropriate.

11.2.2.4 The instructor must be an individual who has demonstrated necessary knowledge, skills, and abilities by regularly conducting DOT alcohol tests as an STT or BAT, as applicable, for a period of at least a year, who has conducted STT or BAT training, as applicable, under 49 CFR Part 40 for a year, or who has successfully completed a "train the trainer" course.

11.2.3 Initial Proficiency Demonstration.

Following completion of qualification training under paragraph 11.2.2 the technician must demonstrate proficiency in alcohol testing under 49 CFR Part 40 by completing three consecutive error-free mock tests.

11.2.3.1 Another person must monitor and evaluate the tested person's performance, in person or by a means that provides real-time observation and interaction between the instructor and trainee, and attest in writing that the mock collections are "error-free." This person must be an individual who meets the requirements of paragraph 11.2.2.4 of this section.

11.2.3.2 These tests must use the alcohol testing devices (e.g., EBT(s) or ASD(s)) that the person tested will use as a BAT or STT.

11.2.3.3 An STT who will be using an ASD that indicates readings by changes, contrasts, or other readings in color, the person tested must demonstrate, as part of the mock test, the ability to discern changes, contrasts, or readings correctly.

11.2.4 Schedule for Qualification Training and the Initial Proficiency Demonstration:

11.2.4.1 Persons who became a BAT or STT before August 1, 2001, were required to have met the requirements set forth in paragraphs 11.2.2 and 11.2.3, and do not have to meet them again.

11.2.4.2 Persons who become a BAT or STT on or after August 1,2001, must meet the requirements of paragraphs 11.2.2 and 11.2.3 before beginning to perform BAT or STT functions.

11.2.5 Refresher Training.

No less frequently than every five years from the date on which a technician satisfactorily complete the requirements of paragraphs 11.2.2 and 11.2.3, the technician must complete refresher training that meets all the requirements of paragraphs 11.2.2 and 11.2.3.

11.2.6 Error Correction Training. If a technician makes a mistake in the alcohol testing process that causes a test to be cancelled (i.e., a fatal or uncorrected flaw), that technician must undergo error correction training. This training must occur within 30 days of the date the technician is notified of the error that led to the need for retraining.

11.2.6.1 Error correction training must be provided and the technician's proficiency documented in writing by a person who meets the requirements of paragraph 11.2.2.4.

11.2.6.2 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.

11.2.6.3 As part of the error correction training, the technician must demonstrate proficiency in the alcohol testing procedures of 49 CFR Part 40 by completing three consecutive error-free mock tests. The mock tests must include one uneventful scenario and two scenarios related to the area(s) in which error(s) occurred. The person providing the training must monitor and evaluate the technician's performance and attest in writing that the mock tests were error-free.

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

11.2.8 Other Persons Who May Serve as BATs or STTs.

11.2.8.1 Anyone meeting the requirements of this section to be a BAT may act as an STT, provided that the individual has demonstrated initial proficiency in the operation of the ASD that he or she is using, as provided in paragraph 11.2.3.

11.2.8.2 Law enforcement officers who have been certified by state or local governments to conduct breath alcohol testing are deemed to be qualified as BATs. They are not required to also complete the training requirements of this section in order to act as BATs. In order for a test conducted by such an officer to be accepted under DOT alcohol testing requirements, the officer must have been certified by a state or local government to use the EBT or ASD that was used for the test.

11.3 Information to Be Given to STTs and BATs. (§40.215)

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

11.4 Additional Information. (§40.217)

Additional information on the role of STTs and BATs can be found in the following sections:

3.1 - definitions.
12.2 - responsibility for supervising employees being tested.
12.3-12.4 - use of the alcohol testing form.
13.1-13.3 - screening test procedures with ASDs and EBTs.
14.1-14.3.1 - confirmation test procedures.
15.1 - refusals to test.
15.2-15.3 - insufficient saliva or breath.
15.4 - problems requiring cancellation of tests
15.5-15.6 - correcting problems in tests.

12. Testing Sites, Forms, Equipment and Supplies Used in Alcohol Testing.

12.1 Where an Alcohol Test Takes Place. (§40.221)

12.1.1 Location. A DOT alcohol test must take place at an alcohol testing site meeting the requirements of this section.

12.1.2 Security Requirements. An alcohol testing site must meet the security requirements of Section 12.2.

12.1.3 Privacy. The person operating an alcohol testing site must ensure that it provides visual and aural privacy to the employee being tested, sufficient to prevent unauthorized persons from seeing or hearing test results.

12.1.4 Requirements to Be Provided. The person operating an alcohol testing site must ensure that it has all needed personnel, materials, equipment, and facilities to provide for the collection and analysis of breath and/or saliva samples, and a suitable clean surface for writing.

12.1.5 Partial Satisfaction of Requirements. If an alcohol testing site fully meeting all the visual and aural privacy requirements of paragraph 12.1.3 is not readily available, 49 CFR Part 40 allows a reasonable suspicion or post-accident test to be conducted at a site that partially meets these requirements. In this case, the site must afford visual and aural privacy to the employee to the greatest extent practicable.

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

12.2 Steps Which Must Be Taken to Protect the Security of Alcohol Testing Sites. (§40.223)

12.2.1 No Unauthorized Personnel. The BAT, STT, or other person operating an alcohol testing site must prevent unauthorized personnel from entering the testing site.

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

12.2.1.2 The BAT or STT must ensure that all persons are under the supervision of a BAT or STT at all times when permitted into the site.

12.2.1.3 The BAT or STT may remove any person who obstructs, interferes with, or causes unnecessary delay in the testing process.

12.2.2 Who May Witness Testing.

The BAT or STT, must not allow any person other than the BAT or STT, the employee, or a DOT agency representative to actually witness the testing process (see Sections 13.1 - 14.3).

12.2.3 Testing Device Must Be Stored in a Secure Place When Not in Use.

The person operating an alcohol testing site must ensure that when an EBT or ASD is not being used for testing it is stored in a secure place.

12.2.4 Limited Access When EBT Unsecured.

The person operating an alcohol testing site must ensure that no one other than BATs or other employees of the site have access to the site when an EBT is unsecured.

12.2.5 Only One Employee May Be Tested at a time.

A BAT or STT, to avoid distraction that could compromise security, is limited to conducting an alcohol test for only one employee at a time.

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

12.2.5.2 A BAT, who will conduct both the screening and the confirmation test, is to complete the entire screening and confirmation process on one employee before starting the screening process on another employee.

12.2.5.3 The BAT or STT is not allowed to leave the alcohol testing site while the testing process for a given employee is in progress, except to notify a supervisor or contact a DER for assistance in the case of an employee or other person who obstructs, interferes with, or unnecessarily delays the testing process.

12.3 Form Used For an Alcohol Test. (§40.225)

12.3.1 ATF Must Be Used.

The DOT Alcohol Testing Form (ATF) must be used for every DOT alcohol test. The ATF must be a three-part carbonless manifold form. The ATF is found in Appendix G to 49 CFR Part 40. This form may be viewed on the ODAPC web site (http://www.dot.gov/ost/dapc).

12.3.2 Permitted Modifications of ATF.

An employer in the DOT alcohol testing program is not permitted to modify or revise the ATF except as follows:

12.3.2.1 An employer may include other information needed for billing purposes, outside the boundaries of the form.

12.3.2.2 An employer may use an ATF directly generated by an EBT which omits the space for affixing a separate printed result to the ATF, provided the EBT prints the result directly on the ATF.

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

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

12.3.2.5 A BAT or STT, may add, on the "Remarks" line of the ATF, the

name of the DOT agency under whose authority the test occurred.

12.3.2.6 A BAT or STT may use an ATF that has his or her name, address, and telephone number preprinted, but under no circumstances can a signature be preprinted.

12.3.3 Foreign Language ATF.

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

12.4 Use of the ATF for Non-DOT tests, or Non-DOT Forms for DOT Tests. (§40.227)

12.4.1 Only ATF Can Be Used for DOT Testing.

An employer, BAT, or STT, is prohibited from using the ATF for non-DOT alcohol tests. Non-DOT forms may not be used for DOT alcohol tests. Doing either subjects the employer to enforcement action under DOT agency regulations.

12.4.2 Effect of Use of Non-DOT Form.

If the STT or BAT, either by mistake, or as the only means to conduct a test under difficult circumstances (e.g., post-accident test with insufficient time to obtain the ATF), uses a non-DOT form for a DOT test, the use of a non-DOT form does not, in and of itself, require the employer or service agent to cancel the test. However, in order for the test to be considered valid, a signed statement must be obtained from the STT or BAT in accordance with paragraph 15.6.2.

12.5 EBTs and ASDs That May Be Used for Screening. (§40.229)

EBTs and ASDs on the NHTSA conforming products lists (CPL) for evidential and non-evidential devices are the only devices that are allowed to be use to conduct alcohol screening tests under 49 CFR Part 40. An ASD can be used only for screening tests for alcohol, and may not be used for confirmation tests.

12.6 Devices Used to Conduct Alcohol Confirmation Tests. (§40.23l)

12.6.1 EBTs That Can Be Used for Confirmatory Tests.

EBTs on the NHTSA CPL for evidential devices that meet the requirements of paragraph 12.6.2 are the only devices that may be used to conduct alcohol confirmation tests under 49 CFR Part 40. Note that, among devices on the CPL for EBTs, only those devices listed without an asterisk (*) are authorized for use in confirmation testing in the DOT alcohol testing program.

12.6.2 Required Capabilities of EBT.

To conduct a confirmation test an EBT that has the following capabilities must be used:

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

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

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

12.6.2.4 Distinguishes alcohol from acetone at the 0.02 alcohol concentration level;

12.6.2.5 Tests an air blank; and

12.6.2.6 Performs an external calibration check.

12.7 Requirements for Proper Use and Care of EBTs. (§40.233)

12.7.1 Quality Assurance Plan Required.

An EBT manufacturer must submit, for NHTSA approval, a quality assurance plan (QAP) for its EBT before NHTSA places the EBT on the CPL.

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

12.7.1.2 The QAP must also specify the inspection, maintenance, and calibration requirements and intervals for the EBT.

12.7.2 Instructions for Use.

The manufacturer must include with each EBT, instructions for its use and care consistent with the QAP.

12.7.3 Procedure.

The user of the EBT (e.g., employer, service agent) must do the following:

12.7.3.1 The user must follow the manufacturer's instructions (see paragraph 12.7.2), including performance of external calibration checks at the intervals the instructions specify.

12.7.3.2 In conducting external calibration checks the user must use only calibration devices appearing on NHTSA's CPL for "Calibrating Units for Breath Alcohol Tests."

12.7.3.3 If an EBT fails an external check of calibration, the user must take the EBT out of service. The EBT may not be used again for DOT alcohol testing until it is repaired and passes an external calibration check.

12.7.3.4 The user must maintain records of the inspection, maintenance, and calibration of EBTs as provided in paragraph 17.6.1.3.

12.7.3.5 The user must ensure that inspection, maintenance, and calibration of the EBT are performed by its manufacturer or a maintenance representative certified either by the manufacturer or by a state health agency or other appropriate state agency.

12.8 Requirements for Proper Use and Care of ASDs. (§40.235)

12.8.1 Quality Assurance Plan.

An ASD manufacturer must submit, for NHTSA approval, a QAP for its ASD before

NHTSA places the ASD on the CPL. The QAP must specify the methods used for quality control checks, temperatures at which the ASD must be stored and used, the shelf life of the device, and environmental conditions (e.g., temperature, altitude, humidity) that may affect the ASD's performance.

12.8.2 Instructions for Use.

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

12.8.3 Procedure.

The user of the ASD (e.g., employer, STT) must follow the QAP instructions.

12.8.4 Unauthorized ASDs.

The user is not permitted to use an ASD that does not pass the specified quality control checks or that has passed its expiration date.

12.8.5 Employers Bound.

An employer, with respect to breath ASDs, must also follow the device use and care requirements of Section 12.8.

13. Alcohol Screening Tests.

13.1 Procedure. (§40.241)

The BAT or STT will take the following steps to begin all alcohol screening tests, regardless of the type of testing device used:

13.1.1 Employee Does Not Appear. When a specific time for an employee's test has been scheduled, or the collection site is at the employee worksite, 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, BAT or STT 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.

13.1.2 No Delay in Testing. The BAT or STT must ensure that, when the employee enters the alcohol testing site, the alcohol testing process begins without undue delay. For example, the BAT or STT must not wait because the employee says he or she is not ready or because an authorized employer or employee representative is delayed in arriving.

13.1.2.1 If the employee is also going to take a DOT drug test, the BAT or STT must, to the greatest extent practicable, ensure that the alcohol test is completed before the urine collection process begins.

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

13.1.3 Employee Must Provide Positive ID. The employee is required to provide positive identification. The BAT or STT must see a photo ID issued by the employer (other than in the case of an owner-operator or other self-employer individual) or a

Federal, state, or local government (e.g., a driver's license). Faxes or photocopies of identification are not acceptable. Positive identification by an employer representative (not a co-worker or another employee being tested) is also acceptable. If the employee cannot produce positive identification, a DER must be contacted to verify the identity of the employee.

13.1.4 BAT or STT Identification. If the employee asks, the BAT or STT must provide identification to the employee. The identification must include the BAT or STT's name and employer's name but is not required to include a picture, address, or telephone number.

13.1.5 Explain Procedure. Explain the testing procedure to the employee, including showing the employee the instructions on the back of the ATF.

13.1.6 Complete Step 1 of the ATF.

13.1.7 Complete Step 2. Direct the employee to complete Step 2 on the ATF and sign the certification. If the employee refuses to sign this certification, the BAT or STT must document this refusal on the "Remarks" line of the ATF and immediately notify the DER. This is a refusal to test.

13.2 Testing Procedure EBT. (§40.243)

The BAT or STT, must take the following steps for an alcohol screening test using an EBT or non-evidential breath ASD.

13.2.1 Select Mouthpiece. Select, or allow the employee to select, an individually wrapped or sealed mouthpiece from the testing materials.

13.2.2 Put Mouthpiece on Device. Open the individually wrapped or sealed mouthpiece in view of the employee and insert it into the device in accordance with the manufacturer's instructions.

13.2.3 Instruct Employee on Procedure. Instruct the employee to blow steadily and forcefully into the mouthpiece for at least six seconds or until the device indicates that an adequate amount of breath has been obtained.

13.2.4 Show the Employee the Displayed Test Result.

13.2.5 Check Printed Result. If the device is one that prints the test number, testing device name and serial number, time, and result directly onto the ATF, check to ensure that the information has been printed correctly onto the ATF.

13.2.6 Put Printed Result on ATF. If the device is one that prints the test number, testing device name and serial number, time and result, but on a separate printout rather than directly onto the ATF, affix the printout of the information to the designated space on the ATF with tamper-evident tape or use a self-adhesive label that is tamper-evident.

13.2.7 Record Information on ATF. If the device is one that does not print the test number, testing device name and serial number, time, and result, or it is a device not being used with a printer, record this information in Step 3 of the ATF.

13.3 Testing procedure Saliva ASD or Breath Tube ASD.

13.3.1 Procedure for Saliva ASD. (§40.245) The SIT or BAT must take the following steps for an alcohol screening test using a saliva ASD.

13.3.1.1 Check the expiration date on the device or on the package containing the device and show it to the driver. The device may not be used after its expiration date.

13.3.1.2 Open an individually wrapped or sealed package containing the device in the presence of the driver.

13.3.1.3 Offer the driver the opportunity to use the device. If the driver uses it, instruct the driver to insert it into his or her mouth and use it in a manner described by the device's manufacturer.

13.3.1.4 If the driver chooses not to use the device, or in all cases in which a new test is necessary because the device did not activate (see paragraph 13.3.1.7), insert the device into the driver's mouth and gather saliva in the manner described by the device's manufacturer. The technician must wear single use examination or similar gloves while doing so and change them following each test.

13.3.1.5 When the device is removed from the driver's mouth, follow the manufacturer's instructions regarding necessary next steps in ensuring that the device has activated.

13.3.1.6 Procedure - Unsuccessful Test.

13.3.1.6.1 If the procedures of paragraphs 13.3.1.3 through 13.3.1.5 were not able to be successfully followed (e.g., the device breaks, the device drops on the floor), discard the device and conduct a new test using a new device.

13.3.1.6.2 The new device used must be one that has been under the technician's control or that of the Employer before the test.

13.3.1.6.3 Note on the "Remarks" line of the ATF the reason for the new test. (Note: the same ATF with which was used to begin the test may continue to be used.)

13.3.1.6.4 The driver must be offered the choice of using the device or having the STT or BAT use it unless the driver, in the opinion of the STT or BAT, was responsible (e.g., the driver dropped the device) for the new test needing to be conducted.

13.3.1.6.5 If the procedures of paragraphs 13.3.1.3 through 13.3.1.5 are unable to successfully be followed on the new test, the collection must be ended and put an explanation on the "Remarks" line of the ATF.

13.3.1.6.6 Direct the driver to take a new test immediately, using an EBT for the screening test.

13.3.1.7 If the procedures of paragraphs 13.3.1.3 through 13.3.1.5 are

successfully followed, but the device does not activate, the STT or BAT must discard the device and conduct a new test, in the same manner as provided in paragraph 13.3.1.6. In this case, the BAT or STT must place the device into the driver's mouth to collect saliva for the new test.

13.3.1.8 Read the result displayed on the device no sooner than the device's manufacturer instructs. In all cases the result displayed must be read within 15 minutes of the test. The BAT or STT must then show the device and its reading to the driver and enter the result on the ATF.

13.3.1.9 Never re-use devices, swabs, gloves or other materials used in saliva testing.

13.3.1.10 Note the fact that a saliva ASD was used in Step 3 of the ATF.

13.3.2 Procedure For Using a Breath Tube ASD.

13.3.2.1 Check the expiration date on the device or on the package containing the device and show it to the driver. The device must not be used after its expiration date.

13.3.2.2 Remove a device from the package and break the tube's ampule in the presence of the driver.

13.3.2.3 Secure an inflation bag onto the appropriate end of the device, as directed by the manufacturer on the device's instructions.

13.3.2.4 Offer the driver the opportunity to use the device. If the driver chooses to use (hold) the device, instruct the driver to blow forcefully and steadily into the blowing end of device until the inflation bag fills with air (approximately 12 seconds).

13.3.2.5 If the driver chooses not to hold the device, the STT or BAT must hold it and provide the use instructions in paragraph 13.3.2.4.

13.3.2.6 When the driver completes the breath process, take the device from the driver (or if the STT or BAT was holding it, remove it from the driver's mouth); remove the inflation bag; and either hold the device or place it on a clean flat surface while waiting for the reading to appear.

13.3.2.7 Procedure – Unsuccessful Test.

13.3.2.7.1 If the procedures of paragraphs 13.3.2.4 through 13.3.2.6 were unable to be successfully followed, (for example., the device breaks apart, the driver did not fill the inflation bag), discard the device and conduct a new test using a new device.

13.3.2.7.2 The new device you use must be one that has been under the STT or BAT's control or that of the employer before the test.

13.3.2.7.3 Note on the "Remarks" line of the ATF the reason for the new test. The same ATF with which was used to begin the test may continue to be used.

13.3.2.7.4 The driver must be offered the choice of holding the device or having the STT or BAT hold it unless the driver, in the opinion of the STT or BAT, was responsible (for example, the driver failed to fill the inflation bag) for the new test needing to be conducted.

13.3.2.7.5 If the procedures of paragraphs 13.3.2.4 through 13.3.2.6 are unable to be successfully followed on the new test, the collection must be ended and an explanation put on the "Remarks" line of the ATF.

13.3.2.7.6 The driver must then be directed to take a new test immediately, using another type of ASD (for example a saliva device) or an EBT.

13.3.2.8 If the procedures of paragraphs 13.3.2.4 through 13.3.2.6 were able to be successfully followed, the STT or BAT must compare the color of the crystals in the device with the colored crystals on the manufacturer-produced control tube no sooner than the manufacturer instructs. In all cases color comparisons must take place within 15 minutes of the test.

13.3.2.9 Follow the manufacturer's instructions for determining the result of the test. Then show both the device and the control tube side-by-side to the driver and record the result on the ATF.

13.3.2.10 Devices or gloves used in breath tube testing must never be re-used. The inflation bag must be voided of air following removal from a device. One inflation bag can be used for up to 10 breath tube tests.

13.3.2.11 Note the fact that a breath tube device was used in Step 3 of the ATF.

13.4 Procedures the BAT or STT Follow After a Screening Test Result. (§40.247)

13.4.1 Procedure If Result less than .02. If the test result is an alcohol concentration of less than 0.02, the BAT or STT must do the following:

13.4.1.1 Sign and date Step 3 of the ATF: and

13.4.1.2 Transmit the result to the DER in a confidential manner, as provided in Section 14.3.

13.4.2 When Confirmatory Test Required. If the test result is an alcohol concentration of 0.02 or higher, the BAT or STT, must direct the employee to take a confirmation test.

13.4.2.1 The BAT who will conduct the confirmation test must then conduct the test using the procedures beginning at Section 14.1.

13.4.2.2 If a different BAT from the one who conducted the screening test will conduct the confirmation test, direct the employee to take a confirmation test, sign and date Step 3 of the ATF, and give the employee Copy 2 of the ATF.

13.4.2.3 If the confirmation test will be performed at a different site from

the screening test, the following additional steps must be taken:

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

13.4.2.3.2 Tell the employee the reason for the waiting period required by paragraph 14.1.1 (i.e., to prevent an accumulation of mouth alcohol from leading to an artificially high reading);

13.4.2.3.3 Explain that following the instructions concerning the waiting period is to the employee's benefit;

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

13.4.2.3.5 Note on the "Remarks" line of the ATF that the waiting period instructions were provided;

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

13.4.2.3.7 The BAT or STT must ensure that he or she or another BAT, STT, or employer representative observe the employee as he or she is transported to the confirmation testing site. The BAT or STT must direct the employee not to attempt to drive a motor vehicle to the confirmation testing site.

13.4.3 Invalid Test.

If the screening test is invalid, the BAT or STT, will tell the employee the test is cancelled and note the problem on the "Remarks" line of the ATF. If practicable, repeat the testing process (see Section 15.6).

14. Alcohol Confirmation Tests.

14.1 The BAT Must Follow These Steps to Begin Alcohol Confirmation Test Process. (§40.251)

14.1.1 Waiting Period.

A waiting period must be observed before the confirmation test, by taking the following steps:

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

14.1.1.1.1 If the confirmation test is taking place at a different location from the screening test (see paragraph 13.4.2.3) the time of transit between sites counts toward the waiting period if the STT or BAT who conducted the screening test provided the waiting period instructions.

14.1.1.1.2 If the BAT cannot verify, through review of the ATF,

that waiting period instructions were provided, then the BAT must carry out the waiting period requirement.

14.1.1.1.3 The BAT conducting the confirmatory test or another BAT or STT, or an employer representative, must observe the employee during the waiting period.

14.1.1.2 Concerning the waiting period, the BAT must tell the employee:

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

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

14.1.1.2.3 That following the BAT's instructions concerning the waiting period is to the employee's benefit; and

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

14.1.1.3 If the BAT becomes aware that the employee has not followed the instructions, this must be noted on the "Remarks" line of the ATF.

14.1.2 Employee Must Present Positive ID.

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

14.1.3 Complete Step 1 of the ATF.

14.1.4 Complete Step 2 of ATF.

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

14.1.5 No Additional Screening Test.

Even if more than 30 minutes have passed since the screening test result was obtained, the BAT must begin the confirmation test procedures in Section 14.2, not another screening test.

14.1.6 Time Between Tests Noted.

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

14.1.7 Late Confirmation Effect.

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

14.2 Confirmatory Test Procedures. (§40.253)

The BAT conducting an alcohol confirmation test must follow these steps to complete the confirmation test process:

14.2.1 Conduct an Air Blank.

In the presence of the employee conduct an air blank on the EBT being used before beginning the confirmation test and show the reading to the employee.

14.2.1.1 If the reading is 0.00, the test may proceed. If the reading is greater than 0.00, conduct another air blank.

14.2.1.2 If the reading on the second air blank is 0.00, the test may proceed. If the reading is greater than 0.00, the EBT must be taken out of service.

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

14.2.1.4 Proceed with the test of the employee using another EBT, if one is available.

14.2.2 Select a New Mouthpiece.

Open a new individually wrapped or sealed mouthpiece in view of the employee and insert it into the device in accordance with the manufacturer's instructions.

14.2.3 Read Test Number.

The BAT must ensure that the BAT and the employee read the sequential test number displayed on the EBT.

14.2.4 Instruct the Employee on Use.

The BAT must instruct the employee to blow steadily and forcefully into the mouthpiece for at least six seconds or until the device indicates that an adequate amount of breath has been obtained.

14.2.5 Show Employee the Result Displayed.

Show the employee the result displayed on the EBT.

14.2.6 Show Employee the Test Result.

Show the employee the result and unique test number that the EBT prints out either directly onto the ATF or onto a separate printout.

14.2.7 Attach Printout to ATF.

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

14.3 Procedure after the Alcohol Confirmation Test Result.

14.3.1 Procedure (§40.255)

After the EBT has printed the result of an alcohol confirmation test the BAT must take the following additional steps:

14.3.1.1 Sign and date Step 3 of the ATF.

14.3.1.2 If the alcohol confirmation test result is lower than 0.02, nothing further is required of the employee. The BAT must sign and date Step 3 of the ATF.

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

14.3.1.4 If the test is invalid, tell the employee the test is cancelled and note the problem on the "Remarks" line of the ATF. If practicable, conduct a re-test. (see Section 15.6).

14.3.1.5 Immediately transmit the result directly to the DER in a confidential manner.

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

14.3.1.5.2 If the BAT does not make the initial transmission in writing, the BAT must follow up the initial transmission with Copy 1 of the ATF.

14.3.2 Employer Procedure on Receipt of Result.

An employer must take the following steps with respect to the receipt and storage of alcohol test result information:

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

14.3.2.2 All test result information must be stored in a way that protects confidentiality.

15. Problems in Alcohol Testing.

15.1 Refusal to Take an Alcohol Test and its Consequences. (§40.26l)

15.1.1 What Constitutes Refusal to Test.

An employee is considered to have refused to take an alcohol test if:

15.1.1.1 The employee fails to appear for any test within a reasonable time, as determined by the employer, after being directed to do so by the employer. This includes the failure of an employee (including an owner-operator) to appear for a test when called by C/TPA (see paragraph 13.1.1);

15.1.1.2 Fails to remain at the testing site until the testing process is complete;

15.1.1.3 Fails to attempt to provide a saliva or breath specimen, as applicable, for any test required by 49 CFR Part 40 or DOT agency regulations;

15.1.1.4 Fails to provide a sufficient breath specimen, and the physician has determined, through a required medical evaluation, that there was no adequate medical explanation for the failure (see paragraph 15.3.3);

15.1.1.5 Fails to undergo a medical examination or evaluation, as directed by the employer as part of the insufficient breath procedures outlined at paragraph 15.3.3;

15.1.1.6 Fails to sign the certification at Step 2 of the ATF (see paragraph 13.1.7); or

15.1.1.7 Fails to cooperate with any part of the testing process.

15.1.2 Consequences of Refusal to Test.

An employee who refuses to take an alcohol test incurs the same consequences specified under DOT agency regulations for a violation of those DOT agency regulations.

15.1.3 Notification to DER.

A BAT or an STT, or physician evaluating a "shy lung" situation must, when an employee refuses to test as provided in paragraph 15.1.1, terminate the portion of the testing process in progress, document the refusal on the ATF (or in a separate document which is to be attached to the form), immediately notify the DER by any means (e.g., telephone or secure fax machine) that ensures the refusal notification is immediately received. This notification must be made directly to the DER (not using a C/TPA as an intermediary).

15.1.4 Effect of Refusal to Take Non-DOT Test.

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 such a refusal.

15.2 Result When an Employee Is Unable to Provide a Sufficient Amount of Saliva for an Alcohol Screening Test. (§40.263)

15.2.1 Procedure.

The STT must take the following steps if an employee is unable to provide sufficient saliva to complete a test on a saliva screening device (e.g., the employee does not provide sufficient saliva to activate the device).

15.2.1.1 Conduct a new screening test using a new screening device.

15.2.1.2 If the employee refuses to make the attempt to complete the new test, the STT must discontinue testing, note the fact on the "Remarks" line of the ATF, and immediately notify the DER. This is a refusal to test.

15.2.1.3 If the employee has not provided a sufficient amount of saliva to complete the new test, the STT must note the fact on the "Remarks" line of the ATF and immediately notify the DER.

15.2.2 DER Responsibilities.

When the STT informs the DER that the employee has not provided a sufficient amount of saliva (see paragraph 15.2.1.3), the DER must immediately arrange to administer an alcohol test to the employee using an EBT or other breath testing device.

15.3 Result When an Employee Is Unable to Provide a Sufficient Amount of Breath for an Alcohol Test. (§40.265)

15.3.1 Procedure.

If an employee does not provide a sufficient amount of breath to permit a valid breath test, take the steps listed in this section.

15.3.2 Second Attempt.

The BAT or STT must instruct the employee to attempt again to provide a sufficient amount of breath and about the proper way to do so.

15.3.2.1 If the employee refuses to make the attempt, discontinue the test, note the fact on the "Remarks" line of the ATF, and immediately notify the DER. This is a refusal to test.

15.3.2.2 If the employee again attempts and fails to provide a sufficient amount of breath, another opportunity may be provided to the employee to do so if the BAT or STT believes that there is a strong likelihood that it could result in providing a sufficient amount of breath.

15.3.2.3 When the employee's attempts under paragraph 15.3.2.2 have failed to produce a sufficient amount of breath, note the fact on the "Remarks" line of the ATF and immediately notify the DER.

15.3.2.4 If an EBT is being used that has the capability of operating manually, the test may be attempted in manual mode.

15.3.2.5 If the BAT or STT is qualified to use a saliva ASD and the testing is in the screening test stage, the BAT or STT may change to a saliva ASD only to complete the screening test.

15.3.3 Evaluation by a Physician.

When the BAT or STT informs the employer that the employee has not provided a sufficient amount of breath, the employer must direct the employee to obtain, within five days, an evaluation from a licensed physician who is acceptable to the employer and who has expertise in the medical issues raised by the employee's failure to provide a sufficient specimen.

15.3.3.1 The employer is required to provide the physician who will

conduct the evaluation with the following information and instructions:

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

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

15.3.3.1.3 That the physician must provide a signed statement of his or her conclusions; and

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

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

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

15.3.3.1.4.3 For purposes of paragraphs 15.3.3.1.4.1 and 15.3.3.1.4.2, a medical condition includes an ascertainable physiological condition (e.g., a respiratory system dysfunction) or a medically documented pre-existing psychological disorder, but does not include unsupported assertions of "situational anxiety" or hyperventilation.

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

15.3.3.3 Upon receipt of the report from the examining physician, the DER must immediately inform the employee and take appropriate action based upon applicable DOT agency regulations.

15.4 Fatal flaws. (§40.267)

An employer, a BAT, or an STT, must cancel an alcohol test if any of the following problems occur. These are "fatal flaws." The DER must be informed that the test was cancelled and must be treated as if the test never occurred. These problems are:

15.4.1 Saliva or Breath Tube ASD. In the case of a screening test conducted on a saliva ASD or breath tube ASD:

15.4.1.1 The STT or BAT reads the result either sooner than or later than the time allotted by the manufacturer (see paragraph 13.3.1.8 for a saliva ASD and paragraph 13.3.2.8 for a breath tube ASD);

15.4.1.2 The saliva ASD device does not activate (see paragraph 13.3.1.7); or

15.4.1.3 The device is used for a test after the expiration date printed on the device or on its package (see paragraph 13.3.1.1 for a saliva ASD and paragraph 13.3.2.1 for a breath tube ASD).

15.4.2 EBT. In the case of a screening or confirmation test conducted on an EBT, the sequential test number or alcohol concentration displayed on the EBT is not the same as the sequential test number or alcohol concentration on the printed result (see paragraphs 14.2.3, 14.2.5 and 14.2.6).

15.4.3 In the case of a confirmation test:

15.4.3.1 The BAT conducts the confirmation test before the end of the minimum 15 minute waiting period (see paragraph 14.1.1.1);

15.4.3.2 The BAT does not conduct an air blank before the confirmation test (see paragraph 14.2.1);

15.4.3.3 There is not a 0.00 result on the air blank conducted before the confirmation test (see paragraph 14.2.1.1 and 14.2.1.2);

15.4.3.4 The EBT does not print the result (see paragraph 14.2.6); or

15.4.3.5 The next external calibration check of the EBT produces a result that differs by more than the tolerance stated in the QAP from the known value of the test standard. In this case, every result of 0.02 or above obtained on the EBT since the last valid external calibration check is cancelled (see paragraphs 12.7.1.1 and 12.7.3.3).

15.5 Correctable Flaws. (§40.269)

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

15.5.1 The BAT or STT Does Not Sign the ATF. (see paragraphs 13.4.1.1 and 14.3.1.1).

15.5.2 Failure to Note Employee's Failure to Sign. The BAT or STT fails to note on the "Remarks" line of the ATF that the employee has not signed the ATF after the result is obtained (see paragraph l4.3.1.3).

15.5.3 Non-DOT Form.

The BAT or STT uses a non-DOT form for the test (see paragraph 12.4.2).

15.6 Correcting Alcohol Testing Problems. (§40.271)

15.6.1 BAT or STT Responsible for Trying to Correct Problems.

A BAT or SIT has the responsibility of trying to complete successfully an alcohol test for each employee.

15.6.1.1 If, during or shortly after the testing process, the BAT or STT becomes aware of any event that will cause the test to be cancelled (see Section 15.4), the BAT or STT must try to correct the problem promptly, if practicable. The BAT or STT may repeat the testing process as part of this effort.

15.6.1.2 If repeating the testing process is necessary, the BAT or STT must begin a new test as soon as possible. The BAT or STT must use a new ATF, a new sequential test number, and, if needed, a new ASD and/or a new EBT. It is permissible to use additional technical capabilities of the EBT (e.g., manual operation) if the BAT or STT has been trained to do so in accordance with Section 11.2.

15.6.1.3 If repeating the testing process is necessary, the BAT or STT is not limited in the number of attempts to complete the test, provided that the employee is making a good faith effort to comply with the testing process.

15.6.1.4 If another testing device is not available for the new test at the testing site, the DER must immediately be notified and advised that the test could not be completed. The DER who receives this information must make all reasonable efforts to ensure that the test is conducted at another testing site as soon as possible.

15.6.2 Person Discovering Flaw Must Try to Correct It.

If a STT, BAT, employer or other service agent administering the testing process becomes aware of a "correctable flaw" (see Section 15.5) that has not already been corrected, the party discovering the correctable flaw must take all practicable action to correct the problem so that the test is not cancelled.

15.6.2.1 If the problem resulted from the omission of required information, the person responsible for providing that information, must supply in writing the missing information and a signed statement that it is true and accurate. For example, suppose a BAT forgot to make a notation on the "Remarks" line of the ATF that the employee did not sign the certification. That BAT would, when the problem is called to the BAT's attention, supply a signed statement that the employee failed or refused to sign the certification after the result was obtained, and that the signed statement is true and accurate.

15.6.2.2 If the problem is the use of a non-DOT form, the person responsible for the use of the incorrect form, must certify in writing that the incorrect form contains all the information needed for a valid DOT alcohol test. The person responsible must also provide a signed statement that the incorrect form was used inadvertently or as the only means of conducting a test, in circumstances beyond the person's control, and the steps taken to prevent future use of non-DOT forms for DOT tests. This information must be supplied on the same business day on which the person responsible is notified of the problem, transmitting it by fax or courier.

15.6.3 If a Problem Cannot Be Corrected, the Test Must Be Cancelled.

15.7 The Effect of a Cancelled Alcohol Test. (§40.273)

15.7.1 A Cancelled Alcohol Test Is Neither Positive Nor Negative.

15.7.1.1 An employer must not attach to a cancelled test the consequences of a test result that is 0.02 or greater (e.g., removal from a safety-sensitive position).

15.7.1.2 An employer must not use a cancelled test in a situation where an employee needs a test result that is below 0.02 (e.g., in the case of a return-to-duty or follow-up test to authorize the employee to perform safety-sensitive functions).

15.7.1.3 An employer must not direct a recollection for an employee because a test has been cancelled, except in the situations cited in paragraph 15.7.1.2 or other provisions of 49 CFR Part 40.

15.7.2 A Cancelled Test Does Not Count Toward Compliance with DOT Requirements.

A cancelled test does not count toward compliance with DOT requirements, such as a minimum random testing rate.

15.7.3 DER Must Be Informed.

When a test must be cancelled the BAT, STT, or other person who determines that the cancellation is necessary must inform the affected DER within 48 hours of the cancellation.

15.7.4 Cancelled Test Not the Basis for a Non-DOT Test.

A cancelled DOT test does not provide a valid basis for an employer to conduct a non-DOT test (i.e., a test under Employer authority).

15.8 Effect of Procedural Problems That Are Not Sufficient to Cancel an Alcohol Test. (§40.275)

15.8.1 Documentary Errors.

A STT, BAT, employer, or a service agent administering the testing process must document any errors in the testing process of which the party becomes aware, even if they are not "fatal flaws" or "correctable flaws" listed in this subpart. Decisions about the ultimate impact of these errors will be determined by administrative or legal proceedings, subject to the limitation of paragraph 15.8.2.

15.8.2 No Cancellation for Certain Errors.

No person concerned with the testing process may declare a test cancelled based on a mistake in the process that does not have a significant adverse effect on the right of the employee to a fair and accurate test. For example, it is inconsistent with 49 CFR Part 40 to cancel a test based on a minor administrative mistake (e.g., the omission of the employee's middle initial) or an error that does not affect employee protections under 49 CFR Part 40. Nor does the failure of an employee to sign in Step 4 of the ATF result in the cancellation of the test. Nor is a test to be cancelled on the basis of a claim by an employee that he or she was improperly selected for testing.

15.8.3 Consequences of Errors.

These errors, even though not sufficient to cancel an alcohol test result, may subject an employer to enforcement action under DOT agency regulations.

15.9 No Other Tests Authorized. (§40.277)

No other types of alcohol tests (e.g., blood and urine) are authorized for testing done under 49 CFR Part 40. Only saliva or breath for screening tests and breath for confirmation tests using approved devices are permitted.

16. Substance Abuse Professional (SAP) and the Return-to-Duty Process.

16.1 Requirements. (§40.281)

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

16.1.1 Credentials.

The person must have one of the following credentials:

16.1.1.1 Licensed physician (Doctor of Medicine or Osteopathy);

16.1.1.2 Licensed or certified social worker;

16.1.1.3 A licensed or certified psychologist;

16.1.1.4 A licensed or certified employee assistance professional;

16.1.1.5 A state-licensed or certified marriage and family therapist; or

16.1.1.6 A drug and alcohol counselor certified by the National Association of Alcoholism and Drug Abuse Counselors Certification Commission (NAADAC) or by the International Certification Reciprocity

Consortium/Alcohol and Other Drug Abuse (ICRC); or by the National Board for Certified Counselors, Inc. and Affiliates/Master Addictions Counselor (NBCC).

16.1.2 Basic Knowledge.

The person must be knowledgeable in the following areas:

16.1.2.1 Be knowledgeable about and have clinical experience in the diagnosis and treatment of alcohol and controlled substances related disorders.

16.1.2.2 Be knowledgeable about the SAP function as it relates to employer interests in safety-sensitive duties.

16.1.2.3 Be knowledgeable about 49 CFR Part 40, the DOT agency regulations applicable to the employers for whom the SAP evaluates employees, and the DOT SAP Guidelines, and keep current on any changes to these materials. These documents are available from ODAPC (Department of Transportation, 400 7th Street, S.W., Room 10403, Washington DC, 20590 (202-366-3784), or on the ODAPC web site (http://www.dot.gov/ost/dapc).

16.1.3 Qualification Training.

The person must receive qualification training meeting the following requirements:

16.1.3.1 Qualification training must provide instruction on the following subjects:

16.1.3.1.1 Background, rationale, and coverage of the Department's drug and alcohol testing program;

16.1.3.1.2 49 CFR Part 40 and DOT agency drug and alcohol testing rules;

16.1.3.1.3 Key DOT drug testing requirements, including collections, laboratory testing, MRO review, and problems in drug testing;

16.1.3.1.4 Key DOT alcohol testing requirements, including the testing process, the role of BATs and STTs, and problems in alcohol tests;

16.1.3.1.5 SAP qualifications and prohibitions;

16.1.3.1.6 The role of the SAP in the return-to-duty process, including the initial employee evaluation, referrals for education and/or treatment, the follow-up evaluation, continuing treatment recommendations, and the follow-up testing plan;

16.1.3.1.7 SAP consultation and communication with employers, MROs, and treatment providers;

16.1.3.1.8 Reporting and record keeping requirements; and

16.1.3.1.9 Issues that SAPs confront in carrying out their duties under the program.

16.1.3.2 Following completion of qualification training under paragraph 16.1.3.1, the person must satisfactorily complete an examination administered by a nationally recognized professional or training organization. The examination must comprehensively cover all the elements of qualification training listed in paragraph 16.1.3.1.

16.1.3.3 The following is the schedule for required qualification training:

16.1.3.3.1 Persons who became a SAP before August 1, 2001 must meet the qualification training requirement no later than December 31, 2003.

16.1.3.3.2 Persons who become a SAP between August 1, 2001, and December 31, 2003, must meet the qualification training requirement no later than December 31, 2003.

16.1.3.3.3 Persons who become a SAP on or after January 1, 2004, must meet the qualification training requirement before beginning to perform SAP functions.

16.1.4 Continuing Education.

During each three-year period from the date on which a person satisfactorily complete the examination under paragraph 16.1.3.2, the person must complete continuing education consisting of at least 12 professional development hours (e.g., CEUs) relevant to performing SAP functions.

16.1.4.1 This continuing education must include material concerning new technologies, interpretations, recent guidance, rule changes, and other information about developments in SAP practice, pertaining to the DOT program, since the time the SAP last met the qualification training requirements of this section.

16.1.4.2 The continuing education activities must include documentable assessment tools to assist the SAP in determining whether he or she has adequately learned the material.

16.1.5 Documentation.

The SAP must maintain documentation showing that he or she currently meets all requirements of this section. This documentation must be provided on request to DOT agency representatives and to employers and C/TPAs who .are using or contemplating using the SAP's services.

16.2 Method for a Certification Organization to Obtain Recognition for its Members as SAP's. (§40.283)

16.2.1 Petition for Inclusion.

Certification organizations that want DOT to authorize its certified drug and alcohol counselors to be added to paragraph 16.1.1.6, may submit a written petition to DOT requesting a review of the petition for inclusion.

16.2.2 Obtain Accreditation.

The applicant must obtain the National Commission for Certifying Agencies

(NCCA) accreditation before DOT will act on the petition.

16.2.3 Meet Minimum Requirements.

The applicant must also meet the minimum requirements of Appendix E to 49 CFR Part 40 before DOT will act on the petition.

16.3 When a SAP Evaluation is Required. (§40.285)

16.3.1 Employee Who Has Violated Drug and Alcohol Regulations.

An employee who has violated DOT drug and alcohol regulations cannot again perform any DOT safety-sensitive duties for any employer until and unless the employee completes the SAP evaluation, referral, and education/treatment processes set forth in this subpart and in applicable DOT agency regulations. The first step in this process is a SAP evaluation.

16.3.2 Must Have a SAP Evaluation Before Return to Duty.

For purposes of this subpart, a verified positive DOT drug test result, a DOT alcohol test with a result indicating an alcohol concentration of 0.04 or greater, a refusal to test (including by adulterating or substituting a urine specimen) or any other violation of the prohibition on the use of alcohol or drugs under a DOT agency regulation constitutes a DOT drug and alcohol regulation violation.

16.4 List of SAPs Must Be Provided to Each Employee Who Violates Drug and Alcohol Regulations. (§40.287)

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

16.5 Employer's Requirements to Provide SAP and Treatment Services to Employees. (§40.289)

16.5.1 No Treatment Required to Be Provided.

An employer is not required to provide a SAP evaluation or any subsequent recommended education or treatment for an employee who has violated a DOT drug and alcohol regulation.

16.5.2 Must Have SAP Evaluation Before Return to Duty.

However, if an employer does offer that employee an opportunity to return to a DOT safety-sensitive duty following a violation, the employer must, before the employee again performs that duty, ensure that the employee receives an evaluation by a SAP meeting the requirements of Section 16.1 and that the employee successfully complies with the SAP's evaluation recommendations.

16.5.3 Payment.

Payment for SAP evaluations and services is left for employers and employees to decide and may be governed by existing management-labor agreements and health care benefits.

16.6 Role of SAP. (§40.291)

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

16.6.1 The SAP Is Charged With:

16.6.1.1 Making a face-to-face clinical assessment and evaluation to determine what assistance is needed by the employee to resolve problems associated with alcohol and/or drug use;

16.6.1.2 Referring the employee to an appropriate education and/or treatment program;

16.6.1.3 Conducting a face-to-face follow-up evaluation to determine if the employee has actively participated in the education and/or treatment program and has demonstrated successful compliance with the initial assessment and evaluation recommendations;

16.6.1.4 Providing the DER with a follow-up drug and/or alcohol testing plan for the employee; and

16.6.1.5 Providing the employee and employer with recommendations for continuing education and/or treatment.

16.6.2 SAP Not an Advocate.

A SAP is not an advocate for the employer or employee. The SAP's function is to protect the public interest in safety by professionally evaluating the employee and recommending appropriate education/treatment, follow-up tests, and aftercare.

16.7 SAP Duties. (§40.293)

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

16.7.1 Assessment.

Provide a comprehensive face-to-face assessment and clinical evaluation.

16.7.2 Recommend Treatment.

Recommend a course of education and/or treatment with which the employee must demonstrate successful compliance prior to returning to DOT safety-sensitive duty.

16.7.2.1 The SAP must make such a recommendation for every individual who has violated a DOT drug and alcohol regulation.

16.7.2.2 The SAP must make a recommendation for education and/or treatment that will, to the greatest extent possible, protect public safety in the event that the employee returns to the performance of safety-sensitive functions.

16.7.3 Appropriate Education.

Appropriate education may include, but is not limited to, self-help groups (e.g., Alcoholics Anonymous) and community lectures, where attendance can be independently verified, and bona fide drug and alcohol education courses.

16.7.4 Appropriate Treatment.

Appropriate treatment may include, but is not limited to, in-patient hospitalization, partial in-patient treatment, out-patient counseling programs, and aftercare.

16.7.5 Written Report to DER.

The SAP must provide a written report directly to the DER highlighting his or her

specific recommendations for assistance (see paragraph 16.16.3).

16.7.6 SAP Assumptions.

For purposes of the SAP's role in the evaluation process, the SAP must assume that a verified positive test result has conclusively established that the employee committed a DOT drug and alcohol regulation violation. The SAP must not take into consideration in any way, as a factor in determining what the SAP's recommendation will be, any of the following:

16.7.6.1 A claim by the employee that the test was unjustified or inaccurate;

16.7.6.2 Statements by the employee that attempt to mitigate the seriousness of a violation of a DOT drug or alcohol regulation (e.g., related to assertions of use of hemp oil, "medical marijuana" use, "contact positives," poppy seed ingestion, job stress); or

16.7.6.3 Personal opinions the SAP may have about the justification or rationale for drug and alcohol testing.

16.7.7 Consultation with MRO.

In the course of gathering information for purposes of evaluation in the case of a drug-related violation, the SAP may consult with the MRO. The MRO is required to cooperate with the SAP and provide available information the SAP requests. It is not necessary to obtain the consent of the employee to provide this information.

16.8 Second SAP Evaluation. (§40.295)

16.8.1 Second Evaluation Not Permitted.

An employee with a DOT drug and alcohol regulation violation, who has been evaluated by a SAP, must not seek a second SAP's evaluation in order to obtain another recommendation.

16.8.2 If Second Evaluation Obtained, It May Not Be Relied Upon.

An employer must not seek a second SAP's evaluation if the employee has already been evaluated by a qualified SAP. If the employee, contrary to paragraph 16.8.1, has obtained a second SAP evaluation, an employer may not rely on it for any purpose under 49 CFR Part 40.

16.9 Who Has the Authority to Change a SAP's Initial Evaluation. (§40.297)

16.9.1 Except as Specified, No One May Change a SAP Evaluation.

Except as provided in paragraph 16.9.2, no one (e.g., an employer, employee, a managed-care provider, any service agent) may change in any way the SAP's evaluation or recommendations for assistance. For example, a third party is not permitted to make more or less stringent a SAP's recommendation by changing the SAP's evaluation or seeking another SAP's evaluation.

16.9.2 Evaluating SAP May Change the Original Evaluation.

The SAP who made the initial evaluation may modify his or her initial evaluation and recommendations based on new or additional information (e.g., from an education or treatment program).

16.10 Limits on the SAP's Discretion. (§40.299)

The SAP's role and the limits on a SAP's discretion in referring employees for education and treatment.

16.10.1 Serve as a Referral Source.

A SAP, upon determination of the best recommendation for assistance, will serve as a referral source to assist the employee's entry into a education and/or treatment program.

16.10.2 Avoid Conflict of Interest.

To prevent the appearance of a conflict of interest, a SAP must not refer an employee requiring assistance to the SAP's private practice or to a person or organization from which the SAP receives payment or to a person or organization in which the SAP has a financial interest. The SAP is precluded from making referrals to entities with which the SAP is financially associated.

16.10.3 Exceptions.

There are four exceptions to the prohibitions contained in paragraph 16.10.2. A SAP may refer an employee to any of the following providers of assistance, regardless of the SAP's relationship with them:

16.10.3.1 A public agency (e.g., treatment facility) operated by a state, county, or municipality;

16.10.3.2 The employer or a person or organization under contract to the employer to provide alcohol or drug treatment and/or education services (e.g., the employer's contracted treatment provider);

16.10.3.3 The sole source of therapeutically appropriate treatment under the employee's health insurance program (e.g., the single substance abuse in-patient treatment program made available by the employee's insurance coverage plan); or

16.10.3.4 The sole source of therapeutically appropriate treatment reasonably available to the employee (e.g., the only treatment facility or education program reasonably located within the general commuting area).

16.11 SAP's Function in the Follow-up Evaluation of an Employee. (§40.30l)

16.11.1 Re-evaluation.

A SAP, after prescribing assistance under Section 16.7, must re-evaluate the employee to determine if the employee has successfully carried out the education and/or treatment recommendations.

16.11.1.1 This is the SAP's way to gauge for the employer the employee's ability to demonstrate successful compliance with the education and/or treatment plan.

16.11.1.2 The SAP's evaluation may serve as one of the reasons the employer decides to return the employee to safety-sensitive duty.

16.11.2 Re-evaluation Determination.

The SAP making the follow-up evaluation determination must:

16.11.2.1 Confer with or obtain appropriate documentation from the appropriate education and/or treatment program professionals where the employee was referred; and

16.11.2.2 Conduct a face-to-face clinical interview with the employee to

determine if the employee demonstrates successful compliance with the SAP's initial evaluation recommendations.

16.11.3 Successful Compliance.

16.11.3.1 If the employee has demonstrated successful compliance, the SAP must provide a written report directly to the DER highlighting the clinical determination that the employee has done so with the SAP's initial evaluation recommendation (see paragraph 16.16.4).

16.11.3.2 The SAP may determine that an employee has successfully demonstrated compliance even though the employee has not yet completed the full regimen of education and/or treatment recommended or needs additional assistance. For example, if the employee has successfully completed the 30-day in-patient program prescribed, the SAP may make a "successful compliance" determination even though the SAP concludes that the employee has not yet completed the out-patient counseling recommended or should continue in an aftercare program.

16.11.4 No Successful Compliance.

16.11.4.1 If the SAP believes, as a result of the follow-up evaluation, that the employee has not demonstrated successful compliance with the SAP's recommendations, the SAP must provide written notice directly to the DER (see paragraph 16.16.5).

16.11.4.2 An employer who receives the SAP's written notice that the employee has not successfully complied with the SAP's recommendations must not return the employee to the performance of safety-sensitive duties.

16.11.4.3 The SAP may conduct additional follow-up evaluation(s) if the employer determines that doing so is consistent with the employee's progress as the SAP has reported it and with the employer's policy and/or labor-management agreements.

16.11.4.4 The employer, following a SAP report that the employee has not demonstrated successful compliance, may take personnel action consistent with the employer's policy and/or labor-management agreements.

16.12 Procedure if the SAP Believes the Employee Needs Additional Help. (§40.303)

Procedure if the SAP believes the employee needs additional treatment, aftercare, or support group services even after the employee returns to safety-sensitive duties.

16.12.1 SAP Response.

If a SAP believes that ongoing services (in addition to follow-up tests) are needed to assist an employee to maintain sobriety or abstinence from drug use after the employee resumes the performance of safety-sensitive duties, the SAP must provide recommendations for these services in the follow-up evaluation report (see paragraph 16.16.4.10).

16.12.2 Employer Requirements of Employee.

An employer receiving a recommendation for these services from a SAP, may, as part of a return-to-duty agreement with the employee, require the employee to participate in the recommended services. The employer may monitor and document

the employee's participation in the recommended services. The employer may also make use of SAP and employee assistance program (EAP) services in assisting and monitoring employees' compliance with SAP recommendations. Nothing in this section permits an employer to fail to carry out its obligations with respect to follow-up testing (see Section 16.15).

16.12.3 Employee Obligation.

An employee is obligated to comply with the SAP's recommendations for these services. If an employee fails or refuses to do so, the employee may be subject to disciplinary action by the employer.

16.13 Conclusion of the Return-to-duty Process. (§40.305)

16.13.1 Return-to-Duty Test.

If the employer decides that it wants to permit the employee to return to the performance of safety-sensitive functions, the employer must ensure that the employee takes a return-to-duty test. This test cannot occur until after the SAP has determined that the employee has successfully complied with prescribed education and/or treatment. The employee must have a negative drug test result and/or an alcohol test with an alcohol concentration of less than 0.02 before resuming performance of safety-sensitive duties.

16.13.2 No Return-to-Duty Before Test Complete.

An employer must not return an employee to safety-sensitive duties until the employee meets the conditions of paragraph 16.13.1. However, the employer is not required to return an employee to safety-sensitive duties because the employee has met these conditions. That is a personnel decision that the employer has the discretion to make, subject to collective bargaining agreements or other legal requirements.

16.13.3 Fitness for Duty Determination.

A SAP or MRO must not make a "fitness for duty" determination as part of this re-evaluation unless required to do so under an applicable DOT agency regulation. It is the employer who must decide whether to put the employee back to work in a safety-sensitive position.

16.14 SAP's Function in Prescribing the Employee's Follow-up Tests. (§40.307)

16.14.1 Written Testing Plan.

A SAP must establish for each employee who has committed a DOT drug or alcohol regulation violation, and who seeks to resume the performance of safety-sensitive functions a written follow-up testing plan. The SAP does not establish this plan until after the SAP determines that the employee has successfully complied with the SAP's recommendations for education and/or treatment.

16.14.2 Copy of Plan to DER.

The SAP must present a copy of this plan directly to the DER (see paragraph 16.16.4.9).

16.14.3 SAP Sole Determiner of Required Follow up Tests.

The SAP is the sole determiner of the number and frequency of follow-up tests and whether these tests will be for drugs, alcohol, or both, unless otherwise directed by the appropriate DOT agency regulation. For example, if the employee had a positive drug test, but the SAP's evaluation or the treatment program professionals determined that the employee had an alcohol problem as well, the SAP should require that the employee have follow-up tests for both drugs and alcohol.

16.14.4 Minimum Testing.

The SAP must, at a minimum, direct that the employee be subject to six unannounced follow-up tests in the first 12 months of safety-sensitive duty following the employee's return to safety-sensitive functions.

16.14.4.1 The SAP may require a greater number of follow-up tests during the first 12-month period of safety-sensitive duty (e.g., the SAP may require one test a month during the 12-month period; or two tests per month during the first 6-month period and one test per month during the final 6-month period).

16.14.4.2 The SAP may also require follow-up tests during the 48 months of safety-sensitive duty following this first 12-month period.

16.14.4.3 The SAP is not to establish the actual dates for the follow-up tests prescribed. The decision on specific dates to test is the employer's.

16.14.4.4 The employer must not impose additional testing requirements (e.g., under Employer authority) on the employee that go beyond the SAP's follow-up testing plan.

16.14.5 Requirements Follow Employee.

The requirements of the SAP's follow-up testing plan "follow the employee" to subsequent employers or through breaks in service.

Example 1: The employee returns to duty with Employer A. Two months afterward, after completing the first two of six follow-up tests required by the SAP's plan, the employee quits his job with Employer A and begins to work in a similar position for Employer B. The employee remains obligated to complete the four additional tests during the next 10 months of safety-sensitive duty, and Employer B is responsible for ensuring that the employee does so. Employer B learns of this obligation through the inquiry it makes under Section 3.8.

Example 2: The employee returns to duty with Employer A. Three months later, after the employee completes the first two of six follow-up tests required by the SAP's plan, Employer A lays the employee off for economic or seasonal employment reasons. Four months later, Employer A recalls the employee. Employer A must ensure that the employee completes the remaining four follow-up tests during the next nine months.

16.14.6 SAP May Modify Determination.

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

16.15 Employer's Responsibilities. (§40.309)

The employer's responsibilities with respect to the SAP's directions for follow-up tests.

16.15.1 Carry out the SAP's Follow-up Testing Requirements.

The employer must carry out the SAP's follow-up testing requirements. The employer may not allow the employee to continue to perform safety-sensitive functions unless follow-up testing is conducted as directed by the SAP.

16.15.2 Schedule Follow-up Tests.

The employer should schedule follow-up tests on dates of its own choosing, but the employer must ensure that the tests are unannounced with no discernable pattern as to their timing, and that the employee is given no advance notice.

16.15.3 No Substitution of Other Tests.

The employer cannot substitute any other tests (e.g., those carried out under the random testing program) conducted on the employee for this follow-up testing requirement.

16.15.4 A Follow-up Test That Has Been Cancelled Can Not Be Counted.

A follow-up test that has been cancelled can not be counted as a completed test. A cancelled follow-up test must be recollected.

16.16 Requirements Concerning SAP Reports. (§40.311)

16.16.1 Where SAP Reports Sent.

The SAP conducting the required evaluations must send the written reports required by this section in writing directly to the DER and not to a third party or entity for forwarding to the DER (except as provided in paragraph 18.8.5). The SAP may, however, forward the document simultaneously to the DER and to a C/TPA.

16.16.2 No Changes to Reports.

An employer must ensure that it receives SAP written reports directly from the SAP performing the evaluation and that no third party or entity changed the SAP's report in any way.

16.16.3 Required Elements of SAP Report.

The SAP's written report, following an initial evaluation that determines what level of assistance is needed to address the employee's drug and/or alcohol problems, must be on the SAP's own letterhead (and not the letterhead of another service agent) signed and dated by the SAP, and must contain the following delineated items:

16.16.3.1 Employee's name and SSN;

16.16.3.2 Employer's name and address;

16.16.3.3 Reason for the assessment (specific violation of DOT regulations and violation date);

16.16.3.4 Date(s) of the assessment;

16.16.3.5 SAP's education and/or treatment recommendation; and

16.16.3.6 SAP's telephone number.

16.16.4 Follow Up Report of Compliance.

The SAP's written report concerning a follow-up evaluation that determines the employee has demonstrated successful compliance must be on the SAP's own

letterhead (and not the letterhead of another service agent), signed by the SAP and dated, and must contain the following items:

16.16.4.1 Employee's name and SSN;

16.16.4.2 Employer's name and address;

16.16.4.3 Reason for the initial assessment (specific violation of DOT regulations and violation date);

16.16.4.4 Date(s) of the initial assessment and synopsis of the treatment plan;

16.16.4.5 Name of practice(s) or service(s) providing the recommended education and/or treatment;

16.16.4.6 Inclusive dates of employee's program participation;

16.16.4.7 Clinical characterization of employee's program participation;

16.16.4.8 SAP's clinical determination as to whether the employee has demonstrated successful compliance;

16.16.4.9 Follow-up testing plan;

16.16.4.10 Employee's continuing care needs with specific treatment, aftercare, and/or support group services recommendations; and

16.16.4.11 SAP's telephone number.

16.16.5 Follow Up Report of Compliance.

The SAP's written report concerning a follow-up evaluation that determines the employee has demonstrated successful compliance must be on the SAP's own letterhead (and not the letterhead of another service agent), signed by the SAP and dated, and must contain the following items:

16.16.5.1 Employee's name and SSN;

16.16.5.2 Employer's name and address;

16.16.5.3 Reason for the initial assessment (specific violation of DOT regulations and violation date);

16.16.5.4 Date(s) of the initial assessment and synopsis of the treatment plan;

16.16.5.5 Name of practice(s) or service(s) providing the recommended education and/or treatment;

16.16.5.6 Inclusive dates of employee's program participation;

16.16.5.7 Clinical characterization of employee's program participation;

16.16.5.8 SAP's clinical determination as to whether the employee has demonstrated successful compliance;

16.16.5.9 Follow-up testing plan;

16.16.5.10 Employee's continuing care needs with specific treatment, aftercare, and/or support group services recommendations; and

16.16.5.11 SAP's telephone number.

16.16.6 Follow Up Report of Non-compliance. The SAP's written report concerning a follow-up evaluation that determines the employee has not demonstrated successful compliance must be on the SAP's own letterhead (and not the letterhead of another service agent), signed by the SAP and dated, and must contain the following items:

16.16.6.1 Employee's name and SSN;

16.16.6.2 Employer's name and address

16.16.6.3 Reason for the initial assessment (specific DOT violation and date);

16.16.6.4 Date(s) of initial assessment and synopsis of treatment plan;

16.16.6.5 Name of practice(s) or service(s) providing the recommended education and/or treatment;

16.16.6.6 Inclusive dates of employee's program participation;

16.16.6.7 Clinical characterization of employee's program participation;

16.16.6.8 Date(s) of the first follow-up evaluation;

16.16.6.9 Date(s) of any further follow-up evaluation the SAP has scheduled;

16.16.6.10 SAP's clinical reasons for determining that the employee has not demonstrated successful compliance; and

16.16.6.11 SAP's telephone number.

16.16.7 Who Gets the Reports. A SAP must also provide these written reports directly to the employee if the employee has no current employer and to the DOT regulated employer in the event the employee obtains another transportation industry safety-sensitive position.

16.16.8 Record Retention - SAP. A SAP is to maintain copies of reports to employers for 5 years, and employee clinical records in accordance with Federal, state, and local laws regarding record maintenance, confidentiality, and release of information. The SAP must make these records available, on request, to DOT agency representatives (e.g., inspectors conducting an audit or safety investigation) and representatives of the NTSB in an accident investigation.

16.16.9 Record Retention - Employer. An employer must maintain reports from SAPs for 5 years from the date the reports were received.

16.17 Additional Information. (§40.313)

Additional information on the role and functions of SAPs can be found in the following sections:

3.1 - definition.
18.4 - service agent assistance with SAP-required follow-up testing.
18.8 - transmission of SAP reports.
17.4.3 - making SAP reports available to employees on request.
Appendix E - SAP Equivalency Requirements for Certification Organizations.

17. Confidentiality and Release of Information.

17.1 No Release Without Employees' Specific Written Consent. (§40.321)

Except as otherwise provided in this subpart, a service agent or employer 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.

17.1.1 "Third Party" is any person or organization to whom 49 CFR Part 40 does not explicitly authorize or require the transmission of information in the course of the drug or alcohol testing process.

17.1.2 "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 49 CFR Part 40.

17.2 Release of Drug or Alcohol Test Information in Connection with Legal Proceedings. (§40.323)

17.2.1 Legal Proceedings in Which Information May Be Released. An employer may release information pertaining to an employee's drug or alcohol test without the employee's consent in certain legal proceedings.

17.2.1.1 These proceedings include a lawsuit (e.g., a wrongful discharge action), grievance (e.g., an arbitration concerning disciplinary action taken by the employer), or administrative proceeding (e.g., an unemployment compensation hearing) brought by, or on behalf of, an employee and resulting from a positive DOT drug or alcohol test or a refusal to test (including, but not limited to, adulterated or substituted test results).

17.2.1.2 These proceedings also include a criminal or civil action resulting from an employee's performance of safety-sensitive duties, in which a court of competent jurisdiction determines that the drug or alcohol test information sought is relevant to the case and issues an order directing the employer to produce the information. For example, in personal injury litigation following a truck or bus collision, the court could determine that a post-accident drug test result of an employee is relevant to determining

whether the driver or the driver's employer was negligent. The employer is authorized to respond to the court's order to produce the records.

17.2.2 Release to Decision Maker.

In such a proceeding, the employer may release the information to the decision maker in the proceeding (e.g., the court in a lawsuit). The employer 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.

17.2.3 Service Agent Must Comply with Employer Request.

If the employer requests its employee's drug or alcohol testing information from a service agent to use in a legal proceeding as authorized in paragraph 17.2.1 (e.g., the laboratory's data package), the service agent must provide the requested information to the employer.

17.2.4 Notify Employee in Writing.

An employer or service agent must immediately notify the employee in writing of any information release under this section.

17.3 The MRO's Report Medical Information Gathered in the Verification Process. (§40.327)

17.3.1 When the MRO must Report to Third Parties Without Employee Consent.

The MRO must, except as provided in paragraph 17.3.3, report drug test results and medical information learned as part of the verification process to third parties without the employee's consent if the MRO determines, in his or her reasonable medical judgment, that:

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

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

17.3.2 Authorized Third Parties.

The third parties to whom the MRO is 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 paragraph 16.7.7), a DOT agency, or the National Transportation Safety Board in the course of an accident investigation.

17.3.3 Compliance with Foreign Law.

If the law of a foreign country (e.g., Canada) prohibits providing medical information to the employer, that prohibition may be complied with.

17.4 Information Which Laboratories, MROs, and Other Service Agents Must Release to Employees. (§40.329)

17.4.1 MRO as Service Agent.

A 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 party providing the records may charge no more than the cost of preparation and reproduction for copies of these records.

17.4.2 Laboratory.

A 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.

17.4.3 SAP.

A SAP must make available to an employee on request, a copy of all SAP reports (see Section 16.16).

17.5 An Employer or Service Agent Must Release Information under the Following Circumstances. (§40.331)

17.5.1 Consent from Employee.

If an employer 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 information must be provided to the identified person. For example, when an employer receives a written request from a former employee to provide information to a subsequent employer, the employer must do so. In providing the information, the employer must comply with the terms of the employee's consent.

17.5.2 Request of DOT Agency.

An employer must, upon request of DOT agency representatives, provide the following:

17.5.2.1 Access to the employer's facilities used for 49 CFR Part 40 and DOT agency drug and alcohol program functions.

17.5.2.2 All written, printed, and computer-based drug and alcohol program records and reports (including copies of name-specific records or reports), files, materials, data, documents/documentation, agreements, contracts, policies, and statements that are required by 49 CFR Part 40 and DOT agency regulations.

17.5.3 Request of DOT Agency on Service Agent.

A service agent must, upon request of DOT agency representatives, provide the following:

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

17.5.3.2 All written, printed, and computer-based drug and alcohol program records and reports (including copies of name-specific records or reports), files, materials, data, documents/documentation, agreements, contracts, policies, and statements that are required by 49 CFR Part 40 and DOT agency regulations.

17.5.4 Request by NTSB.

If requested by the National Transportation Safety Board as part of an accident investigation, information concerning post-accident tests administered after the accident must be provided.

17.5.5 Request by Safety Agency.

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

17.5.6 Release of Specimen.

Except as otherwise provided in 49 CFR Part 40, a 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 a laboratory to release 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 Section 2.6). 49 CFR Part 40 does not require disobedience of a court order, however.

17.6 Records Employers Must Keep. (§40.333)

17.6.1 Time Records.

An employer must keep the following records for the following periods of time:

17.6.1.1 The following records must be kept for five years:

17.6.1.1.1 Records of employee alcohol test results indicating an alcohol concentration of 0.02 or greater;

17.6.1.1.2 Records of employee verified positive drug test results;

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

17.6.1.1.4 SAP reports; and

17.6.1.1.5 All follow-up tests and schedules for follow-up tests.

17.6.1.2 Information obtained from previous employers under Section 3.8 concerning drug and alcohol test results of employees must be kept for three years.

17.6.1.3 Records of the inspection, maintenance, and calibration of EBTs must be kept for two years.

17.6.1.4 Records of negative and cancelled drug test results and alcohol test results with a concentration of less than 0.02 must be kept for one year.

17.6.2 Records Not Required to Be Kept.

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

17.6.3 Location.

Records must be maintained in a location with controlled access.

17.6.4 Records That May Be Maintained by Service Agent.

A service agent may maintain these records for an employer. However, the employer must ensure that it can produce these records at its principal place of business in the time required by the DOT agency. For example, as a motor carrier, when an FMCSA inspector requests an employer's records, the employer must ensure that it can provide them within two working days.

18. Roles and Responsibilities of Service Agents.

18.1 Service Agents must Comply with DOT Drug and Alcohol Testing Requirements. (§40.341)

18.1.1 Service Agents Must Comply with 49 CFR Part 40.

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

18.1.2 If a Service Agent Fails to Comply with 49 CFR Part 40, It May Be Subject to PIE.

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

18.2 Service Agent Limitations. (§40.343)

A service agent may perform for employers the tasks needed to comply with DOT agency drug and alcohol testing regulations, subject to the requirements and limitations of 49 CFR Part 40.

18.3 C/TPA as Intermediary. (§40.345)

A C/TPA may act as an intermediary in the transmission of drug and alcohol testing information to employers in the following circumstances:

18.3.1 Employer Must Choose to Have C/TPA as an Intermediary.

A 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 employer chooses to have the C/TPA do so. Each employer 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).

18.3.2 When a C/TPA May Act as an Intermediary.

The specific provisions of 49 CFR Part 40 concerning which a 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.

18.3.3 Confidentiality.

In every case, the C/TPA must ensure that, in transmitting information to employers, it 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 employer. For example, if a 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 Section 8.21.

18.4 C/TPA Service in Random Selection. (§40.347)

A C/TPA, except as otherwise specified in 49 CFR Part 40, may perform the following functions for employers concerning random selection and other selections for testing.

18.4.1 Random Testing.

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).

18.4.2 Formation of Pools.

A 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.

18.4.2.1 If a 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.

18.4.2.2 Employees not covered by DOT agency regulations may not be part of the same random pool with DOT covered employees.

18.4.3 Follow Up Testing.

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 employer are permitted to randomly select employees from a "follow-up pool" for follow-up testing.

18.5 Records a Service Agent May Receive and Maintain. (§40.349)

18.5.1 Information Regarding the Testing Program.

Except where otherwise specified in 49 CFR Part 40, a service agent may receive and maintain all records concerning DOT drug and alcohol testing programs, including positive, negative, and refusal to test on individual test results. The C/TPA does not need the employee's consent to receive and maintain these records.

18.5.2 Information Needed For Operating a Drug/Alcohol Program.

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 employers of selected employees) on behalf of an employer.

18.5.3 Copies to C/TPA of Documents Sent to DER.

If a service agent originating drug or alcohol testing information, such as an MRO or BAT, sends the information directly to the DER, he or she may also provide the information simultaneously to a C/TPA or other service agent who maintains this information for the employer.

18.5.4 Time for Forwarding Information.

The party serving as an intermediary in transmitting information that is required to be provided to the employer must ensure that it reaches the employer in the same time periods required elsewhere in 49 CFR Part 40.

18.5.5 Time for Delivering Requested Information.

A C/TPA must ensure that it can make available to the employer within two days any information the employer is asked to produce by a DOT agency representative.

18.5.6 Transfer of Records.

On request of an employer, a C/TPA must, at any time on the request of an employer, transfer immediately all records pertaining to the employer and its employees to the employer or to any other service agent the employer designates. 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 its reasonable administrative costs for conducting this transfer. The C/TPA may not charge a fee for the release of these records.

18.5.7 Notice of C/TPA Merger or Going out of Business.

A C/TPA planning to go out of business or a C/TPA which will be bought by or merged with another organization, 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 its reasonable administrative costs for conducting this transfer. The C/TPA may not charge a fee for the release of these records.

18.6 Confidentiality. (§40.351)

Except where otherwise specified in 49 CFR Part 40 the following confidentiality requirements apply to a service agent:

18.6.1 Service Agent Subject to Same Confidentiality Obligation as Employer.

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

18.6.2 Service Agent Must Follow Confidentiality and Records Retention Requirements Applicable to Employers.

The service agent must follow all confidentiality and records retention requirements applicable to employers.

18.6.3 No Release of Information Without the Specific Written Consent of Employee.

The service agent may not provide individual test results or other confidential information to another employer without a specific, written consent from the employee. For example, suppose C/TPA has employers X and Y as clients. Employee Jones works for X, and C/TPA maintains 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.

18.6.4 No Blanket Consents.

Blanket consent forms authorizing the release of employee testing information must not be used.

18.6.5 Adequate Confidentiality and Security Procedures.

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.

18.7 Principles Govern a Service Agent Other than an MRO. (§40.353)

The following principles govern a service agent other than an MRO (e.g., a C/TPA)'s interaction with MROs:

18.7.1 Comply with 49 CFR Part 40.

A C/TPA may provide MRO services to employers, directly or through contract, if all applicable provisions of 49 CFR Part 40 are met.

18.7.2 If C/TPA Employs or Contracts for MRO, MRO Must Act Independently.

If a C/TPA employs or contracts for an MRO, the MRO must perform duties independently and confidentially. When the C/TPA has a relationship with an MRO, it 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.

18.7.3 MRO Staff Functions.

Only C/TPA staff who are actually under the day-to-day supervision and control of an MRO with respect to MRO functions may perform these functions. This does not mean that those staff may not perform other functions at other times. However, the designation of C/TPA staff to perform MRO functions under MRO supervision must be limited and not used as a subterfuge to circumvent confidentiality and other requirements of 49 CFR Part 40 and DOT agency regulations. The C/TPA must ensure that MRO staff operate under controls sufficient to ensure that the independence and confidentiality of the MRO process are not compromised.

18.7.4 Functions MRO Staff Cannot Perform.

Like other MROs, an MRO employed by or contracted with a C/TPA must personally conduct verification interviews with employees and must personally make all verification decisions. Consequently, staff cannot perform these functions.

18.8 Limitations on Service Agents. (§40.355)

Service agents are subject to the following limitations concerning its activities in the DOT drug and alcohol testing program.

18.8.1 May Not Require an Employee to Sign a Consent, Release, Waiver of Liability, or Indemnification.

Service agents 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).

18.8.2 May Not Act as an Intermediary in the Transmission of Drug Test Results to MRO.

Service agents 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 a service agent's computer system, and the service agent then assign the results to a particular MRO, is not permitted.

18.8.3 May Not Transmit Drug Test Results from the Lab to the Employer.

Service agents must not transmit drug test results directly from the laboratory to the

employer (by electronic or other means) or to a service agent who forwards them to the employer. All confirmed laboratory results must be processed by the MRO before they are released to any other party.

18.8.4 May Not Act as an Intermediary in the Transmission of .02 or Higher Alcohol Results.

Service agents 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.

18.8.5 May Not Act as an Intermediary in the Transmission of SAP Reports.

Except as provided in paragraph 18.8.6, a 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 the service agent 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.

18.8.6 Exception for Owner-Operator.

As an exception to paragraph 18.8.5, a 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.

18.8.7 May Not Make Decisions to Test upon Reasonable Suspicion, Post-accident, Return-to-duty, and Follow-up Determination Criteria.

Except as provided in paragraph 18.8.8, a 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 actual employer cannot delegate to a C/TPA. The C/TPA may, however, provide advice and information to employers regarding these testing issues and how the employer should schedule required testing.

18.8.8 Exception for Owner - Operators.

As an exception to paragraph 18.8.7, a C/TPA 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.

18.8.9 Must Not Make Determinations about Refusal to Test.

Except as provided in paragraph 18.8.10, a C/TPA must not make a determination that an employee has refused a drug or alcohol test. This is a non-delegable duty of the actual employer. A C/TPA may, however, provide advice and information to employers regarding refusal-to-test issues.

18.8.10 Exceptions.

As an exception to paragraph 18.8.9, a service agent may make a determination that an employee has refused a drug or alcohol test, if:

18.8.10.1 If authorized by a DOT agency regulation to do so, when a C/TPA 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

18.8.10.2 A MRO may determine that an individual has refused to test on the basis of adulteration or substitution.

18.8.11 A Service Agent Must Not Act as a DER.

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

18.8.12 Service Agent May Only Send Lab Copy of CCF to the Lab.

In transmitting documents to laboratories, a service agent must ensure that only the laboratory copy of the CCF is sent to the laboratory that conducts testing. No other copies of the CCF or any ATFs may be transmitted to the laboratory.

18.8.13 Service Agent May Not Impose Conditions or Requirements on Employers Not in DOT Regulations.

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

18.8.14 No Intentional Delays.

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

Example 3: 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: 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.

18.8.15 Employer Remains Liable.

While a service agent must follow the DOT agency regulations, the actual employer remains accountable to DOT for compliance, and the service agent's failure to implement any aspect of the program as required in 49 CFR Part 40 and other applicable DOT agency regulations makes the employer subject to enforcement action by the Department.

18.9 Retention of Records. (§382.401)

18.9.1 Requirements.

Each employer shall maintain records of its alcohol misuse and controlled substances

use prevention programs as provided in this section. The records shall be maintained in a secure location with controlled access.

18.9.2 Period of Retention:

18.9.2.1 Five years. The following records shall be maintained for a minimum of five years:

18.9.2.1.1 Records of driver alcohol test results indicating an alcohol concentration of 0.02 or greater;

18.9.2.1.2 Records of driver verified positive controlled substances test results;

18.9.2.1.3 Documentation of refusals to take required alcohol and/or controlled substances tests;

18.9.2.1.4 Driver evaluation and referrals;

18.9.2.1.5 Calibration documentation;

18.9.2.1.6 Records related to the administration of the alcohol and controlled substances testing programs; and

18.9.2.1.7 A copy of each annual calendar year summary required by Section 18.10.

18.9.2.2 Two years. Records related to the alcohol and controlled substances collection process (except calibration of evidential breath testing devices).

18.9.2.3 One year. Records of negative and cancelled controlled substances test results and alcohol test results with a concentration of less than 0.02 shall be maintained for a minimum of one year.

18.9.2.4 Indefinite period. Records related to the education and training of breath alcohol technicians, screening test technicians, supervisors, and drivers shall be maintained by the employer while the individual performs the functions which require the training and for two years after ceasing to perform those functions.

18.9.3 Types of Records to Be Maintained.

The following specific types of records shall be maintained. "Documents generated" are documents that may have to be prepared under a requirement of this part. If the record is required to be prepared, it must be maintained.

18.9.3.1 Records related to the collection process:

18.9.3.1.1 Collection logbooks, if used;

18.9.3.1.2 Documents relating to the random selection process;

18.9.3.1.3 Calibration documentation for evidential breath testing devices;

18.9.3.1.4 Documentation of breath alcohol technician training;

18.9.3.1.5 Documents generated in connection with decisions to administer reasonable suspicion alcohol or controlled substances tests;

18.9.3.1.6 Documents generated in connection with decisions on post-accident tests;

18.9.3.1.7 Documents verifying existence of a medical explanation of the inability of a driver to provide adequate breath or to provide a urine specimen for testing; and

18.9.3.1.8 Consolidated annual calendar year summaries as required by Section 18.10.

18.9.3.2 Records related to a driver's test results:

18.9.3.2.1 The employer's copy of the alcohol test form, including the results of the test;

18.9.3.2.2 The employer's copy of the controlled substances test chain of custody and control form;

18.9.3.2.3 Documents sent by the MRO to the employer.

18.9.3.2.4 Documents related to the refusal of any driver to submit to an alcohol or controlled substances test required by this part;

18.9.3.2.5 Documents presented by a driver to dispute the result of an alcohol or controlled substances test administered under this part; and

18.9.3.2.6 Documents generated in connection with verifications of prior employers' alcohol or controlled substances test results that the employer:

18.9.3.2.6.1 Must obtain in connection with the exception contained in Section 3.1 of this part, and

18.9.3.2.6.2 Must obtain as required by Section 3.8.

18.9.3.3 Records related to other violations of this part.

18.9.3.4 Records related to evaluations:

18.9.3.4.1 Records pertaining to a determination by a substance abuse professional concerning a driver's need for assistance; and

18.9.3.4.2 Records concerning a driver's compliance with recommendations of the substance abuse professional.

18.9.3.5 Records related to education and training:

18.9.3.5.1 Materials on alcohol misuse and controlled substance use awareness, including a copy of the employer's policy on alcohol misuse and controlled substance use;

18.9.3.5.2 Documentation of compliance with the requirements of Section 2.3, including the driver's signed receipt of education materials;

18.9.3.5.3 Documentation of training provided to supervisors for the purpose of qualifying the supervisors to make a determination concerning the need for alcohol and/or controlled substances testing based on reasonable suspicion;

18.9.3.5.4 Documentation of training for breath alcohol technicians; and

18.9.3.5.5 Certification that any training conducted under this part complies with the requirements for such training.

18.9.3.6 Administrative records related to alcohol and controlled substances testing:

18.9.3.6.1 Agreements with collection site facilities, laboratories, breath alcohol technicians, screening test technicians, medical review officers, consortia, and third party service providers;

18.9.3.6.2 Names and positions of officials and their role in the employer's alcohol and controlled substances testing program(s);

18.9.3.6.3 Semi-annual laboratory statistical summaries of urinalysis required by paragraph 7.16.1; and

18.9.3.6.4 The employer's alcohol and controlled substances testing policy and procedures.

18.9.4 Location of Records.

All records required by this part shall be maintained as required by §390.31 and shall be made available for inspection at the employer's principal place of business within two business days after a request has been made by an authorized representative of the FMCSA.

18.10 Reporting of Results in a Management Information System. (§382.403)

18.10.1 Employer Must Maintain Summary.

An employer shall prepare and maintain a summary of the results of its alcohol and controlled substances testing programs performed under Part 382 during the previous calendar year, when requested by the Secretary of Transportation, any DOT agency, or any State or local officials with regulatory authority over the employer or any of its drivers.

18.10.2 Submission of Summary to FMCSA.

If an employer is notified, during the month of January, of a request by the FMCSA to report the employer's annual calendar year summary information, the employer shall prepare and submit the report to the FMCSA by March 15 of that year. The employer shall ensure that the annual summary report is accurate and received by March 15 at the location that the FMCSA specifies in its request. The report shall be in the form and manner prescribed by the FMCSA in its request. When the report is submitted to

the FMCSA by mail or electronic transmission, the information requested shall be typed, except for the signature of the certifying official. Each employer shall ensure the accuracy and timeliness of each report submitted by the employer or a consortium.

18.10.2.1 Type of Form to be Used to Report Management Information System Data.

Employer must use the form and follow the instructions attached as Appendix H ("*Appendix H to Part 40 - DOT Drug and Alcohol Testing Management Information System (MIS) Data Collection Form*") when the employer is required to report Management Information System (MIS) data to a Department of Transportation agency.

18.10.3 Information Required.

Each annual calendar year summary that contains information on a verified positive controlled substances test result, an alcohol screening test result of 0.02 or greater, or any other violation of the alcohol misuse provisions of Section 2.8 shall include the following informational elements:

18.10.3.1 Number of drivers subject to Part 382;

18.10.3.2 Number of drivers subject to testing under the alcohol misuse or controlled substances use rules of more than one DOT agency, identified by each agency;

18.10.3.3 Number of urine specimens collected by type of test (e.g., pre-employment, random, reasonable suspicion, post-accident);

18.10.3.4 Number of positives verified by a MRO by type of test, and type of controlled substance;

18.10.3.5 Number of negative controlled substance tests verified by a MRO by type of test;

18.10.3.6 Number of drivers with tests verified positive by a MRO for multiple controlled substances;

18.10.3.7 Number of drivers who refused to submit to an alcohol or controlled substances test required under this paragraph, including those who submitted substituted or adulterated specimens;

18.10.3.8 Number of screening alcohol tests by type of test; and

18.10.3.9 Number of confirmation alcohol tests, by type of test;

18.10.3.10 Number of confirmation alcohol tests indicating an alcohol concentration of 0.02 or greater but less than 0.04, by type of test;

18.10.3.11 Number of confirmation alcohol tests indicating an alcohol concentration of 0.04 or greater, by type of test;

18.10.3.12 Number of drivers who were found to have violated any non-

testing prohibitions of Section 2.8, and any action taken in response to the violation.

18.10.3.13 Short summary. Each employer's annual calendar year summary that contains only negative controlled substance test results, alcohol screening test results of less than 0.02, and does not contain any other violations of Section 2.8, may prepare and submit either a standard report form containing all the information elements specified in paragraph 18.10.3, or an "EZ" report form. The "EZ" report shall include the following information elements:

18.10.3.13.1 Number of drivers subject to Part 382;

18.10.3.13.2 Number of drivers subject to testing under the alcohol misuse or controlled substance use rules of more than one DOT agency, identified by each agency;

18.10.3.13.3 Number of urine specimens collected by type of test (e.g., pre-employment, random, reasonable suspicion, post-accident);

18.10.3.13.4 Number of negatives verified by a Medical Review Officer by type of test;

18.10.3.13.5 Number of drivers who refused to submit to an alcohol or controlled substances test required under this paragraph;

18.10.3.13.6 Supervisor Training.

18.10.3.13.6.1 Number of supervisors who have received required alcohol training during the reporting period; and

18.10.3.13.6.2 Number of supervisors who have received required controlled substances training during the reporting period.

18.10.3.13.7 Number of screen alcohol tests by type of test; and

18.10.3.13.8 Number of drivers who were returned to duty (having complied with the recommendations of a substance abuse professional as described in Sections 16.7 and 16.13), in this reporting period, who previously:

18.10.3.13.8.1 Had a verified positive controlled substance test result, or

18.10.3.13.8.2 Engaged in prohibited alcohol misuse under the provisions of this part.

18.10.4 Drivers Identified by Agency.

Each employer that is subject to more than one DOT agency alcohol or controlled substances rule shall identify each driver covered by the regulations of more than one DOT agency. The identification will be by the total number of covered

functions. Prior to conducting any alcohol or controlled substances test on a driver subject to the rules of more than one DOT agency, the employer shall determine which DOT agency rule or rules authorizes or requires the test. The test result information shall be directed to the appropriate DOT agency or agencies.

18.10.5 C/TPA May Prepare Report.

A C/TPA may prepare annual calendar year summaries and reports on behalf of individual employers for purposes of compliance with this section. However, each employer shall sign and submit such a report and shall remain responsible for ensuring the accuracy and timeliness of each report prepared on its behalf by a C/TPA.

18.11 Access to Facilities and Records. (§382.405)

18.11.1 Limitation on Release of Driver Information.

Except as required by law or expressly authorized or required in this section, no employer shall release driver information that is contained in records required to be maintained under Section 18.9.

18.11.2 Driver May Request Copies.

A driver is entitled, upon written request, to obtain copies of any records pertaining to the driver's use of alcohol or controlled substances, including any records pertaining to his or her alcohol or controlled substances tests. The employer shall promptly provide the records requested by the driver. Access to a driver's records shall not be contingent upon payment for records other than those specifically requested.

18.11.3 Access to Facilities.

Each employer shall permit access to all facilities utilized in complying with the requirements of this part to the Secretary of Transportation, any DOT agency, or any State or local officials with regulatory authority over the employer or any of its drivers.

18.11.4 Information Shall Be Provided to DOT.

Each employer shall make available copies of all results for employer alcohol and/or controlled substances testing conducted under this part and any other information pertaining to the employer's alcohol misuse and/or controlled substances use prevention program, when requested by the Secretary of Transportation, any DOT agency, or any State or local officials with regulatory authority over the employer or any of its drivers.

18.11.5 Disclosure to NTSB.

When requested by the National Transportation Safety Board as part of an accident investigation, employers shall disclose information related to the employer's administration of a post-accident alcohol and/or controlled substance test administered following the accident under investigation.

18.11.6 Disclosure to Subsequent Employers.

Records shall be made available to a subsequent employer upon receipt of a written request from a driver. Disclosure by the subsequent employer is permitted only as expressly authorized by the terms of the driver's request.

18.11.7 Other Disclosures.

An employer may disclose information required to be maintained under this part pertaining to a driver, the decision maker in a lawsuit, grievance, or other proceeding initiated by or on behalf of the individual, and arising from a positive DOT drug or

alcohol test or a refusal to test (including, but not limited to, adulterated or substituted test results) of this part (including, but not limited to, a worker's compensation, unemployment compensation, or other proceeding relating to a benefit sought by the driver). Additionally, an employer may disclose information in criminal or civil actions in accordance with paragraph 17.2.1.2.

18.11.8 Disclosure by Driver Request.

An employer shall release information regarding a driver's records as directed by the specific, written consent of the driver authorizing release of the information to an identified person. Release of such information by the person receiving the information is permitted only in accordance with the terms of the employee's specific written consent as outlined in paragraph 17.1.2.

19. Public Interest Exclusions.

19.1 Purpose of a Public Interest Exclusion (PIE). (§40.361)

19.1.1 To Protect the Public Interest from Serious Noncompliance.

To protect the public interest, including protecting transportation employers and employees from serious noncompliance with DOT drug and alcohol testing rules, the Department's policy is to ensure that employers conduct business only with responsible service agents.

19.1.2 PIE Used to Show Service Agent Not Currently Acting in a Responsible Manner.

The Department therefore uses PIES to exclude from participation in DOT's drug and alcohol testing program any service agent who, by serious noncompliance with 49 CFR Part 40 or other DOT agency drug and alcohol testing regulations, has shown that it is not currently acting in a responsible manner.

19.1.3 PIE Is a Serious Action.

A PIE is a serious action that the Department takes only to protect the public interest. The DOT intends to use PIES only to remedy situations of serious noncompliance. PIES are not used for the purpose of punishment.

19.1.4 Other Actions Not Precluded.

Nothing in this subpart precludes a DOT agency or the Inspector General from taking other action authorized by its regulations with respect to service agents or employers that violate its regulations.

19.2 Basis for the Issuance of a PIE. (§40.363)

19.2.1 Failure to Comply.

The Department may issue a PIE concerning a service agent if it determines that the service agent has failed or refused to provide drug or alcohol testing services consistent with the requirements of 49 CFR Part 40 or a DOT agency drug and alcohol regulation.

19.2.2 Failure to Cooperate.

The Department also may issue a PIE if a party has failed to cooperate with DOT agency representatives concerning inspections, complaint investigations, compliance and enforcement reviews, or requests for documents and other information about compliance with 49 CFR Part 40 or DOT agency drug and alcohol regulations.

19.3 The Department's Policy Concerning Starting a PIE Proceeding. (§40.365)

19.3.1 PIE Proceeding Only in Cases of Serious, Uncorrected Noncompliance.

It is the Department's policy to start a PIE proceeding only in cases of serious,

uncorrected noncompliance with the provisions of 49 CFR Part 40, affecting such matters as safety, the outcomes of test results, privacy and confidentiality, due process and fairness for employees, the honesty and integrity of the testing program, and cooperation with or provision of information to DOT agency representatives.

19.3.2 Examples.

The following are examples of the kinds of serious noncompliance that, as a matter of policy, the Department views as appropriate grounds for starting a PIE proceeding. These examples are not intended to be an exhaustive or exclusive list of the grounds for starting a PIE proceeding. The Department intends them to illustrate the level of seriousness that the Department believes supports starting a PIE proceeding.

19.3.2.1 For an MRO, verifying tests positive without interviewing the employees as required by 49 CFR Part 40 or providing MRO services without meeting the qualifications for an MRO required by 49 CFR Part 40;

19.3.2.2 For a laboratory, refusing to provide information to the Department, an employer, or an employee as required by 49 CFR Part 40; failing or refusing to conduct a validity testing program when required by 49 CFR Part 40; or a pattern or practice of testing errors that result in the cancellation of tests. (As a general matter of policy, the Department does not intend to initiate a PIE proceeding concerning a laboratory with respect to matters on which HHS initiates certification actions under its laboratory guidelines.);

19.3.2.3 For a collector, a pattern or practice of directly observing collections when doing so is unauthorized, or failing or refusing to directly observe collections when doing so is mandatory;

19.3.2.4 For collectors, BATs, or STTs, a pattern or practice of using forms, testing equipment, or collection kits that do not meet the standards in 49 CFR Part 40;

19.3.2.5 For a collector, BAT, or STT, a pattern or practice of "fatal flaws" or other significant uncorrected errors in the collection process;

19.3.2.6 For a laboratory, MRO or C/TPA, failing or refusing to report tests results as required by 49 CFR Part 40 or DOT agency regulations;

19.3.2.7 For a laboratory, falsifying, concealing, or destroying documentation concerning any part of the drug testing process, including, but not limited to, documents in a "litigation package;"

19.3.2.8 For SAPs, providing SAP services while not meeting SAP qualifications required by 49 CFR Part 40 or performing evaluations without face-to-face interviews;

19.3.2.9 For any service agent, maintaining a relationship with another party that constitutes a conflict of interest under 49 CFR Part 40 (e.g., a laboratory that derives a financial benefit from having an employer use a specific MRO);

19.3.2.10 For any service agent, representing falsely that the service agent

or its activities is approved or certified by the Department or a DOT agency;

19.3.2.11 For any service agent, disclosing an employee's test result information to any party 49 CFR Part 40 or a DOT agency regulation does not authorize, including by obtaining a "blanket" consent from employees or by creating a data base from which employers or others can retrieve an employee's DOT test results without the specific consent of the employee;

19.3.2.12 For any service agent, interfering or attempting to interfere with the ability of an MRO to communicate with the Department, or retaliating against an MRO for communicating with the Department;

19.3.2.13 For any service agent, directing or recommending that an employer fail or refuse to implement any provision of 49 CFR Part 40; or

19.3.2.14 With respect to noncompliance with a DOT agency regulation, conduct that affects important provisions of Department-wide concern (e.g., failure to properly conduct the selection process for random testing).

19.4 The Following DOT Officials May Initiate a PIE Proceeding. (§40.367):

19.4.1 The Drug and Alcohol Program Manager of a DOT Agency;

19.4.2 An Official of ODAPC, Other than the Director; or

19.4.3 The Designee of Any of These Officials.

19.5 Discretion of an Initiating Official in Starting a PIE Proceeding. (§40.369)

19.5.1 Broad Discretion.

Initiating officials have broad discretion in deciding whether to start a PIE proceeding.

19.5.2 Department Policy Must Be Considered.

In exercising this discretion, the initiating official must consider the Department's policy regarding the seriousness of the service agent's conduct (see Section 19.3) and all information he or she has obtained to this point concerning the facts of the case. The initiating official may also consider the availability of the resources needed to pursue a PIE proceeding.

19.5.3 Non Issuance of a PIE Does Not Indicate Compliance by a Service Agent.

A decision not to initiate a PIE proceeding does not necessarily mean that the Department regards a service agent as being in compliance or that the Department may not use other applicable remedies in a situation of noncompliance.

19.6 Information an Official Relies upon in Deciding to Start a PIE. (§40.371)

Information an initiating official relies upon in deciding whether to start a PIE proceeding.

19.6.1 Credible Information.

An initiating official may rely on credible information from any source as the basis for starting a PIE proceeding.

19.6.2 Informal Contact First.

Before sending a correction notice (see Section 19.7), the initiating official informally contacts the service agent to determine if there is any information that

may affect the initiating official's determination about whether it is necessary to send a correction notice. The initiating official may take any information resulting from this contact into account in determining whether to proceed under this subpart.

19.7 Opportunity to Correct Problems Before Starting a PIE Proceeding. (§40.373)

19.7.1 Correction Notice.

The initiating official must send a service agent a correction notice before starting a PIE proceeding.

19.7.2 Identify Specific Areas of Non-compliance.

The correction notice identifies the specific areas in which the service agent must come into compliance in order to avoid being subject to a PIE proceeding.

19.7.3 Compliance by Service Agent.

If the service agent makes and documents changes needed to come into compliance in the areas listed in the correction notice to the satisfaction of the initiating official within 60 days of the date receipt of the notice, the initiating official does not start a PIE proceeding. The initiating official may conduct appropriate fact finding to verify that the service agent has made and maintained satisfactory corrections. When he or she is satisfied that the service agent is in compliance, the initiating official sends the service agent a notice that the matter is concluded.

19.8 Starting a PIE Proceeding. (§40.375)

19.8.1 Notice of Proposed Exclusion (NOPE).

If a service agent's compliance matter is not correctable (see paragraph 19.7.1), or if the service agent has not resolved compliance matters as provided in paragraph 19.7.3, the initiating official starts a PIE proceeding by sending the service agent a notice of proposed exclusion (NOPE). The NOPE contains the initiating official's recommendations concerning the issuance of a PIE, but it is not a decision by the Department to issue a PIE.

19.8.2 The NOPE Includes the Following Information:

19.8.2.1 A statement that the initiating official is recommending that the Department issue a PIE concerning the service agent;

19.8.2.2 The factual basis for the initiating official's belief that the service agent is not providing drug and/or alcohol testing services to DOT-regulated employers consistent with the requirements of 49 CFR Part 40 or that the service agent is in serious noncompliance with a DOT agency drug and alcohol regulation;

19.8.2.3 The factual basis for the initiating official's belief that the service agent's noncompliance has not been or cannot be corrected;

19.8.2.4 The initiating official's recommendation for the scope of the PIE;

19.8.2.5 The initiating official's recommendation for the duration of the PIE; and

19.8.2.6 A statement that the service agent may contest the issuance of the proposed PIE, as provided in Section 19.10.

19.8.3 NOPE Procedure.

The initiating official sends a copy of the NOPE to the ODAPC Director at the same time he or she sends the NOPE to the service agent.

19.9 Procedure for Issuance of a PIE (§40.377)

19.9.1 Decision to Issue a PIE.

The ODAPC Director, or his or her designee, decides whether to issue a PIE. If a designee is acting as the decision maker, all references in this subpart to the Director refer to the designee.

19.9.2 Impartiality.

To ensure his or her impartiality, the Director plays no role in the initiating official's determination about whether to start a PIE proceeding.

19.9.3 Insulation of Director.

There is a "firewall" between the initiating official and the Director. This means that the initiating official and the Director are prohibited from having any discussion, contact, or exchange of information with one another about the matter, except for documents and discussions that are part of the record of the proceeding.

19.10 Contesting the Issuance of a PIE. (§40.379)

19.10.1 A Person Receiving a NOPE, May Contest the Issuance of the PIE.

19.10.2 Presentation of Opposition.

If a person wants to contest the proposed PIE, that person must provide the Director information and argument in opposition to the proposed PIE in writing, in person, and/or through a representative. To contest the proposed PIE, one or more of the steps listed in this paragraph 19.10.2 must be taken within 30 days after receipt of the NOPE.

19.10.2.1 The Director may be asked to dismiss the proposed PIE without further proceedings, on the basis that it does not concern serious noncompliance with 49 CFR Part 40 or DOT agency regulations,

consistent with the Department's policy as stated in Section 19.3.

19.10.2.2 Written information and arguments may be presented, consistent with the provisions of Section 19.11, contesting the proposed PIE.

19.10.2.3 An informal meeting may be arranged with the Director to present information and arguments.

19.10.3 Time to Oppose.

If none of the actions listed in paragraph 19.10.2 are taken within 30 days after receipt of the NOPE, the matter proceeds as an uncontested case. In this event, the Director makes his or her decision based on the record provided by the initiating official (i.e., the NOPE and any supporting information or testimony) and any additional information the Director obtains.

19.11 Information to Present to Contest the Proposed Issuance of a PIE. (§40.381)

19.11.1 Minimum Opposition Information.

A service agent who wants to contest a proposed PIE must present at least the following information to the Director:

19.11.1.1 Specific facts that contradict the statements contained in the NOPE (see paragraphs 19.8.2.2 and 19.8.2.3). A general denial is insufficient to raise a genuine dispute over facts material to the issuance of a PIE;

19.11.1.2 Identification of any existing, proposed or prior PIE; and

19.11.1.3 Identification of affiliates, if any.

19.11.2 Other Information and Arguments.

Any information and arguments the service agent wishes concerning the proposed issuance, scope and duration of the PIE (see paragraph 19.8.2.4 and 19.8.2.5).

19.11.3 Any Additional Relevant Information.

Any additional relevant information or arguments concerning any of the issues in the matter.

19.12 Procedures to Contest the Issuance of a PIE. (§40.383)

19.12.1 Flexible Procedure.

DOT conducts PIE proceedings in a fair and informal manner. The Director may use flexible procedures to allow the service agent to present matters in opposition. The Director is not required to follow formal rules of evidence or procedure in creating the record of the proceeding.

19.12.2 Any Relevant Information Considered.

The Director will consider any information or argument he or she determines to be relevant to the decision on the matter.

19.12.3 Any Documentary Evidence the Service Agent Desires May Be Submitted.

The service agent may submit any documentary evidence it desires the Director to consider. In addition, if an informal meeting with the Director has been arranged, the service agent may present witnesses and confront any person the initiating

official presents as a witness against the service agent.

19.12.4 Fact Finding.

In cases where there are material factual issues in dispute, the Director or his or her designee may conduct additional fact-finding.

19.12.5 Transcript of Director Meeting.

If a meeting with the Director has been arranged, the Director will make a transcribed record of the meeting available to the service agent on the service agent's request. The service agent must pay the cost of transcribing and copying the meeting record.

19.13 The Burden of Proof in a PIE Proceeding. (§40.385)

19.13.1 Initiating Official Has the Burden of Proof.

As the proponent of issuing a PIE, the initiating official bears the burden of proof.

19.13.2 Preponderance of the Evidence Standard.

This burden is to demonstrate, by a preponderance of the evidence, that the service agent was in serious noncompliance with the requirements of 49 CFR Part 40 for drug and/or alcohol testing-related services or with the requirements of another DOT agency drug and alcohol testing regulation.

19.14 Matters the Director Decides Concerning a Proposed PIE. (§40.387)

19.14.1 Steps the Director May Take.

Following the service agent's response (see paragraph 19.10.2) or, if no response is received, after 30 days have passed from the date on which the service agent received the NOPE, the Director may take one of the following steps:

19.14.1.1 In response to a request from the service agent (see paragraph 19.10.2.1) or on his or her own motion, the Director may dismiss a PIE proceeding if he or she determines that it does not concern serious noncompliance with 49 CFR Part 40 or DOT agency regulations, consistent with the Department's policy as stated in Section 19.3.

19.14.1.1.1 If the Director dismisses a proposed PIE under this paragraph 19.20.1, the action is closed with respect to the noncompliance alleged in the NOPE.

19.14.1.1.2 The Department may initiate a new PIE proceeding against the service agent on the basis of different or subsequent conduct that is in noncompliance with 49 CFR Part 40 or other DOT drug and alcohol testing rules.

19.14.1.2 If the Director determines that the initiating official's submission does not have complete information needed for a decision, the Director may remand the matter to the initiating official. The initiating official may resubmit the matter to the Director when the needed information is complete. If the basis for the proposed PIE has changed, the initiating official must send an amended NOPE to the service agent.

19.14.2 Director Determinations.

The Director makes determinations concerning the following matters in any PIE proceeding that he or she decides on the merits:

19.14.2.1 Any material facts that are in dispute;

19.14.2.2 Whether the facts support issuing a PIE;

19.14.2.3 The scope of any PIE that is issued; and

19.14.2.4 The duration of any PIE that is issued.

19.15 Factors the Director May Consider in Mitigation and Aggravation. (§40.389)

Factors the Director may consider in mitigation and aggravation in determining whether to issue a PIE, as well as the scope and duration of a PIE. This list is not exhaustive or exclusive. The Director may consider other factors if appropriate in the circumstances of a particular case.

19.15.1 The Actual or Potential Harm.

The actual or potential harm that results or may result from the service agent's noncompliance.

19.15.2 Frequency of Incidents.

The frequency of incidents and/or duration of the noncompliance.

19.15.3 Pattern or Prior History of Noncompliance.

Whether there is a pattern or prior history of noncompliance.

19.15.4 Pervasiveness of the Non-compliance.

Whether the noncompliance was pervasive within the service agent's organization, including such factors as the following:

19.15.4.1 Whether and to what extent the service agent's organization planned, initiated, or carried out the noncompliance;

19.15.4.2 The positions held by individuals involved in the noncompliance, and whether principals of the service agent tolerated their noncompliance; and

19.15.4.3 Whether the service agent had effective standards of conduct and control systems (both with respect to the service agent's own organization and any contractors or affiliates) at the time the noncompliance occurred.

19.15.5 Service Agent's Compliance Disposition.

Whether the service agent has demonstrated an appropriate compliance disposition, including such factors as the following:

19.15.5.1 Whether the service agent has accepted responsibility for the noncompliance and recognizes the seriousness of the conduct that led to the cause for issuance of the PIE;

19.15.5.2 Whether the service agent has cooperated fully with the Department during the investigation. The Director may consider when the cooperation began and whether the service agent disclosed all pertinent information known to it;

19.15.5.3 Whether the service agent has fully investigated the

circumstances of the noncompliance forming the basis for the PIE and, if so, have made the result of the investigation available to the Director;

19.15.5.4 Whether the service agent has taken appropriate disciplinary action against the individuals responsible for the activity that constitutes the grounds for issuance of the PIE; and

19.15.5.5 Whether the service agent's organization has taken appropriate corrective actions or remedial measures, including implementing actions to prevent recurrence.

19.15.6 Degree to Which the Noncompliance Affects Matters Common to the DOT Drug and Alcohol Testing.

With respect to noncompliance with a DOT agency regulation, the degree to which the noncompliance affects matters common to the DOT drug and alcohol testing program.

19.15.7 Other Appropriate Factors.

Other factors appropriate to the circumstances of the case.

19.16 The Scope of a PIE.

19.16.1 Parties Affected by the PIE.

The scope of a PIE is the Department's determination about the divisions, organizational elements, types of services, affiliates, and/or individuals (including direct employees of a service agent and its contractors) to which a PIE applies.

19.16.2 Applies to All of Service Agent's Divisions Involved in Non-compliance.

If the Department issues a PIE concerning a service agent the PIE applies to all the service agent's divisions, organizational elements, and types of services that are involved with or affected by the noncompliance that forms the factual basis for issuing the PIE.

19.16.3 NOPE Sets Forth the Recommendation for Scope.

In the NOPE (see Section 19.8), the initiating official sets forth his or her recommendation for the scope of the PIE. The proposed scope of the PIE is one of the elements of the proceeding that the service agent may contest (see paragraph 19.11.2) and about which the Director makes a decision (see paragraph 19.20.2.3).

19.16.4 Other Matters Considered.

In recommending and deciding the scope of the PIE, the initiating official and Director, respectively, must take into account the provisions of paragraphs 19.16.5 through 19.16.10.

19.16.5 Pervasiveness Is an Important Consideration.

The pervasiveness of the noncompliance within a service agent's organization (see paragraph 19.15.4) is an important consideration in determining the scope of a PIE. The appropriate scope of a PIE grows broader as the pervasiveness of the noncompliance increases.

19.16.6 Pie Not Limited to Specific Location or Employer.

The application of a PIE is not limited to the specific location or employer at which the conduct that forms the factual basis for issuing the PIE was discovered.

19.16.7 PIE Applies to Service Agent's Affiliates.

A PIE applies to the service agent's affiliates, if the affiliate is involved with or

affected by the conduct that forms the factual basis for issuing the PIE.

19.16.8 Individuals to Which a PIE Applies.

A PIE applies to individuals who are officers, employees, directors, shareholders, partners, or other individuals associated with the service agent's organization in the following circumstances:

19.16.8.1 Conduct forming any part of the factual basis of the PIE occurred in connection with the individual's performance of duties by or on behalf of the service agent's organization; or

19.16.8.2 The individual knew of, had reason to know of, approved, or acquiesced in such conduct. The individual's acceptance of benefits derived from such conduct is evidence of such knowledge, acquiescence, or approval.

19.16.8.2.1 If a contractor to the service agent's organization is solely responsible for the conduct that forms the factual basis for a PIE, the PIE does not apply to the service agent itself unless the service agent knew or should have known about the conduct and did not take action to correct it.

19.16.9 PIE Does Not Apply to Non-DOT Testing.

PIES do not apply to drug and alcohol testing that DOT does not regulate.

19.16.10 Examples. (§40.391)

The following examples illustrate how the Department intends the provisions of this section to work:

Example 1. Service Agent P provides a variety of drug testing services. P's SAP services are involved in a serious violation of 49 CFR Part 40. However, P's other services fully comply with 49 CFR Part 40, and P's overall management did not plan or concur in the noncompliance, which in fact was contrary to P's articulated standards. Because the noncompliance was isolated in one area of the organization's activities, and did not pervade the entire organization, the scope of the PIE could be limited to SAP services.

Example 2. Service Agent Q provides a similar variety of services. The conduct forming the factual basis for a PIE concerns collections for a transit authority. As in Example 1, the noncompliance is not pervasive throughout Q's organization. The PIE would apply to collections at all locations served by Q, not just the particular transit authority or not just in the state in which the transit authority is located.

Example 3. Service Agent R provides a similar array of services. One or more of the following problems exists: R's activities in several areas - collections, MROs, SAPs, protecting the confidentiality of information - are involved in serious noncompliance; DOT determines that R's management knew or should have known about serious noncompliance in one or more areas, but management did not take timely corrective action; or, in response to an inquiry from DOT personnel, R's management refuses to provide information about its operations. In each of these three cases, the scope of the PIE would include all aspects of R's services.

Example 4. Service Agent W provides only one kind of service (e.g., laboratory or MRO services). The Department issues a PIE concerning these services. Because W only provides this one kind of service, the PIE necessarily applies to all its operations.

Example 5. Service Agent X, by exercising reasonably prudent oversight of its

collection contractor, should have known that the contractor was making numerous "fatal flaws" in tests. Contractor, would be subject to a PIE with respect to collections.

Example 6. Service Agent Y could not reasonably have known that one of its MROs was regularly failing to interview employees before verifying tests positive. When it received a correction notice, Y immediately dismissed the erring MRO. In this case, the MRO would be subject to a PIE but Y would not.

Example 7. The Department issues a PIE with respect to Service Agent Z. Z provides services for DOT-regulated transportation employers, a Federal agency under the HHS-regulated Federal employee testing program, and various private businesses and public agencies that DOT does not regulate. The PIE applies only to the DOT-regulated transportation employers with respect to their DOT-mandated testing, not to the Federal agency or the other public agencies and private businesses. The PIE does not prevent the non-DOT regulated entities from continuing to use Z's services.

19.17 Duration of a PIE. (§40.393)

19.17.1 NOPE Proposes the Duration of the PIE.

In the NOPE (see paragraph 19.8.2.5), the initiating official proposes the duration of the PIE. The duration of the PIE is one of the elements of the proceeding that the service agent may contest (see paragraph 19.11.2) and about which the Director makes a decision (see paragraph 19.14.2.4).

19.17.2 Duration Considers the Seriousness of the Conduct Involved.

In deciding upon the duration of the PIE, the Director considers the seriousness of the conduct on which the PIE is based and the continued need to protect employers and employees from the service agent's noncompliance. The Director considers factors such as those listed in Section 19.15 in making this decision.

19.17.3 Duration Between 1 and 5 Years.

The duration of a PIE will be between one and five years, unless the Director reduces its duration under Section 19.24.

19.18 Settling a PIE. (§40.395)

At any time before the Director's decision, the service agent and the initiating official can, with the Director's concurrence, settle a PIE proceeding.

19.19 Time for Director Decision. (§40.397)

The Director makes his or her decision within 60 days of the date when the record of a PIE proceeding is complete (including any meeting with the Director and any additional fact-finding that is necessary). The Director may extend this period for good cause for additional periods of up to 30 days.

19.20 Written Notice to Service Agent. (§40.399)

The Director provides the service agent involved in a PIE proceeding with written notice as soon as he or she makes a PIE decision. The notice includes the following elements:

19.20.1 No PIE.

If the decision is not to issue a PIE, a statement of the reasons for the decision, including findings of fact with respect to any material factual issues that were in dispute.

19.20.2 PIE to Be Issued.

If the decision is to issue a PIE.

19.20.2.1 A reference to the NOPE;

19.20.2.2 A statement of the reasons for the decision, including findings of fact with respect to any material factual issues that were in dispute;

19.20.2.3 A statement of the scope of the PIE; and

19.20.2.4 A statement of the duration of the PIE.

19.21 Department Notification of Employers and the Public about a PIE.

19.21.1 "List of Excluded Drug and Alcohol Service Agents."

The Department maintains a document called the "List of Excluded Drug and Alcohol Service Agents." This document may be found on the Department's web site (http://www.dot.gov/ost/dapc). A copy of the document may also be requested from ODAPC.

19.21.2 Service Agent Added to List.

When the Director issues a PIE, he or she adds to the List the name and address of the service agent, and any other persons or organizations, to whom the PIE applies and information about the scope and duration of the PIE.

19.21.3 Service Agent Removed from List.

When a service agent ceases to be subject to a PIE, the Director removes this information from the List.

19.21.4 Notice in Federal Register.

The Department also publishes a Federal Register notice to inform the public on any occasion on which a service agent is added to or taken off the List.

19.22 A Service Agent's Duty to Notify its Clients When the Department Issues a PIE. (§40.403)

19.22.1 Notice to Clients in Writing.

If the Department issues a PIE concerning a service agent, that service agent must notify each of its DOT-regulated employer clients, in writing, about the issuance, scope, duration, and effect of the PIE. This requirement may be met by sending a copy of the Director's PIE decision or by a separate notice. This notice must be sent to each client within three working days of receiving from the Department the notice provided for in paragraph 19.20.2.

19.22.2 Offer to Transfer Records.

As part of the notice the service agent must send under paragraph 19.22.1 the service agent must offer to transfer immediately all records pertaining to the employer and its employees to the employer or to any other service agent the employer designates. The service agent must carry out this transfer as soon as the employer requests it.

19.23 Director's Decision Is a Final Administrative Action.

The Director's decision is a final administrative action of the Department. Like all final administrative actions of Federal agencies, the Director's decision is subject to judicial review under the Administrative Procedure Act (5 U.S.C. 551 et. seq).

19.24 Procedure for a Service Agent to Ask to Have a PIE Reduced or Terminated. (§40.407)

19.24.1 Request for Termination or Reduction of PIE.

A service agent concerning whom the Department has issued a PIE may request that the Director terminate a PIE or reduce its duration and/or scope. This process is limited to the issues of duration and scope. It is not an appeal or reconsideration of the decision to issue the PIE.

19.24.2 Written Request.

The request must be in writing and supported with documentation.

19.24.3 At Least 9 Month Waiting Period.

A service agent must wait at least nine months from the date on which the Director issued the PIE to make this request.

19.24.4 Initiating Official May Provide Information.

The initiating official who was the proponent of the PIE may provide information and arguments concerning the service agent's request to the Director.

19.24.5 Director May Terminate or Reduce PIE.

If the Director verifies that the sources of the service agent's noncompliance have been eliminated and that all drug or alcohol testing-related services the service agent would provide to DOT-regulated employers will be consistent with the requirements of 49 CFR Part 40, the Director may issue a notice terminating or reducing the PIE.

19.25 What the Issuance of a PIE Means to Transportation Employers. (§40.409)

19.25.1 An Employer Is Deemed to Have Notice of the Issuance of a PIE When It Appears on the List.

An employer is deemed to have notice of the issuance of a PIE when it appears on the List mentioned in paragraph 19.21.1 or the notice of the PIE appears in the Federal Register as provided in paragraph 19.21.4. An employer should check this List to ensure that any service agents it is using or planning to use are not subject to a PIE.

19.25.2 Employer Must Stop Using Service Agent Subject to a PIE Within 90 Days.

An employer who is using a service agent concerning whom a PIE is issued must stop using the services of the service agent no later than 90 days after the Department has published the decision in the Federal Register or posted it on its web site. An employer may apply to the ODAPC Director for an extension of 30 days if it demonstrates that it cannot find a substitute service agent within 90 days.

19.25.3 Employer Must Not Use Service Agent Covered by PIE.

Except during the period provided in paragraph 19.25.2, an employer must not, as an employer, use the services of a service agent that are covered by a PIE that the Director has issued under this subpart. If an employer does so, that employer is in violation of the Department's regulations and subject to applicable DOT agency sanctions (e.g., civil penalties, withholding of Federal financial assistance). (also §382.117).

19.25.4 Employer Must Not Use a Contractor or Affiliate of Service Agent Subject to PIE.

An employer also must not obtain drug or alcohol testing services through a contractor or affiliate of the service agent to whom the PIE applies.

Example. Service Agent R was subject to a PIE with respect to SAP services. An

employer, not only must not use R's own SAP services, but it also must not use SAP services arranged through R, such as services provided by a subcontractor or affiliate of R or a person or organization that receives financial gain from its relationship with R.

19.25.5 Prohibition Applies to Employers in All Industries Subject to DOT.

This section's prohibition on using the services of a service agent concerning which the Director has issued a PIE applies to employers in all industries subject to DOT drug and alcohol testing regulations.

Example. The initiating official for a PIE was the FAA drug and alcohol program manager, and the conduct forming the basis of the PIE pertained to the aviation industry. A motor carrier, transit authority, pipeline, railroad, or maritime employer is also prohibited from using the services of the service agent involved in connection with the DOT drug and alcohol testing program.

19.25.6 Issuance of a PIE Does Not Cancel Drug or Alcohol Tests Conducted Using the Service Agent Involved in a PIE up to 90 Days Following Listing.

The issuance of a PIE does not result in the cancellation of drug or alcohol tests conducted using the service agent involved before the issuance of the Director's decision or up to 90 days following its publication in the Federal Register or posting on the Department's web site, unless otherwise specified in the Director's PIE decision or the Director grants an extension as provided in paragraph 19.25.2.

Example. The Department issues a PIE concerning Service Agent N on September 1. All tests conducted using N's services before September 1, and through November 30, are valid for all purposes under DOT drug and alcohol testing regulations, assuming they meet all other regulatory requirements.

19.26 The Role of the DOT Inspector General's office. (§40.4l1)

19.26.1 Waste, Fraud and Abuse.

Any person may bring concerns about waste, fraud, or abuse on the part of a service agent to the attention of the DOT Office of Inspector General.

19.26.2 Criminal or Civil Remedies.

In appropriate cases, the Office of Inspector General may pursue criminal or civil remedies against a service agent.

19.26.3 Office of Inspector General May Provide Information for PIE Proceeding.

The Office of Inspector General may provide factual information to other DOT officials for use in a PIE proceeding.

19.27 How Notices Are Sent to Service Agents. (§40.413)

19.27.1 Methods of Notice.

DOT sends notices to service agents, including correction notices, notices of proposed exclusion, decision notices, and other notices, in any of the ways mentioned in paragraph 19.27.2 or 19.27.3.

19.27.2 Where Sent.

DOT may send a notice to a service agent, its identified counsel, its agent for service of process, or any of its partners, officers, directors, owners, or joint venturers to the last known street address, fax number, or e-mail address. DOT deems the notice to have been received by the service agent if sent to any of these persons.

19.27.3 When Notice Is Deemed Received.

DOT considers notices to be received by the service agent:

19.27.3.1 When delivered, if DOT mails the notice to the last known street address, or five days after sending it if the letter is undeliverable;

19.27.3.2 When sent, if DOT sends the notice by fax or five days after it is sent if the fax is undeliverable; or

19.27.3.3 When delivered, if DOT sends the notice by e-mail or five days after DOT sends it if the e-mail is undeliverable.

EXHIBIT A

Additional Employer Policies

Employer's additional policies with respect to the use of alcohol or controlled substances, including any consequences for a driver found to have a specified alcohol or controlled substances level, that are based on the Employer's authority independent of 49 CFR Part 382 are attached to the printed version of this Plan.

EXHIBIT B

Company Representative(s), Service Contracts and Collection Sites

1. **DER(S) PRIMARY** **BACKUP:**

2. **Medical Review Officer (MRO)**

Sara A. Rinck, M.D.
16560 Harbor Blvd., Suite A
Fountain Valley, CA 92708
(800) 310-0036

John R. Hollingsworth
16560 Harbor Blvd., Suite A
Fountain Valley, CA 92708
(800) 310-0036

3. **S.A.M.S.H.A. Certified Laboratories**

LabCorp
1904 Alexander Drive
Research Triangle, NC 27709

PacTox
6160 Variel Avenue
Woodland Hills, CA 91367

Pathology Associates Medical Laboratories (PAML)
110 West Cliff Drive
Spokane, WA 99220

4. **Substance Abuse Professionals (SAP)**

Albert Boykin, M.F.C.C., L.C.S.W.
Sehlene LeCornu
6712 Friends Avenue, Suite C
Whittier, CA 90601
Phone: 805-383-1826;
Fax: 805-383-1827

Robert Bruner
Substance Abuse
Professionals Network
1615 Orange Tree Lane, Suite 101
Redlands, CA 92374
Phone: 800-879-6428;
Fax: 909-307-3246

5. **Breath Alcohol Technician (BAT) or Screening Test Technician (STT)**

Central Drug System, Inc. (CDS) may provide on site alcohol testing when requested by the employer. In addition, CDS may refer the employer to a medical facility that has the qualified personnel to conduct alcohol testing. In either circumstance, CDS in conjunction with the employer, will monitor and verify the qualifications of BAT's and STT's for compliance with federal requirements as outlined in this plan. Furthermore, any employee requesting information relating to BAT's or STT's (i.e.; name, qualifications, etc.) used by the employer should contact the DER. The DER will make this information available upon request.

6. **Employee Assistance Program (EAP)**

Albert Boykin, M.F.C.C., L.C.S.W.
Sehlene LeCornu
6712 Friends Avenue, Suite C
Whittier, CA 90601
Phone: 805-383-1826;
Fax: 805-383-1827

Robert Bruner
Substance Abuse
Professionals Network
1615 Orange Tree Lane, Suite 101
Redlands, CA 92374
Phone: 800-879-6428;
Fax: 909-307-3246

7. **Collection Sites.**

CHANGE OF DESIGNATED EMPLOYER REPRESENTATIVE(S) (DER)

Company Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Phone: _____ Ext.: _____

Fax: _____ E-mail _____

Previous DER: _____

New DER: _____

Back-Up DER(s): _____

Phone/Ext: (if different): _____

Back-Up DER(s): _____

Phone/Ext: (if different): _____

Date Effective: _____

Authorized By: _____

If possible, please fax this form to us using your company's letterhead. Thank you.

☞ FAX/MAIL TO:

CENTRAL DRUG SYSTEM, INC.
16560 HARBOR BLVD., SUITE **A**
FOUNTAIN VALLEY, CA 92708
PHONE: 800/310-0036
FAX: 714/418-0137
ATTENTION: MARKETING DEPARTMENT

REQUEST FORM
ADDITIONAL COLLECTION SITE(S)

Name: _____ Date: _____

Company Name: _____

Mailing Address: _____

_____

Phone: _____ Fax: _____

E-Mail: _____

Please indicate the collection site(s) and/or address(es) with zip codes that you would like below:

1. Name of collection site: _____

   Address: _____

   City, State, Zip: _____

   Phone/Fax: _____

   Contact: _____

2. Name of collection site: _____

   Address: _____

   City, State, Zip: _____

   Phone/Fax: _____

   Contact: _____

There will be a $35.00 charge for each additional collection site. Please sign below to authorize this charge and fax to (714) 418-0137. Please remember it takes <u>two weeks</u> for the collection site to receive the necessary supplies.

Authorized By: _____

Central Drug System, Inc.
16560 Harbor Blvd., Suite A, Fountain Valley, CA 92708
800/310-0036; Fax: 714/418-0137

G:\Marketing Dept\Policy Notebook\AddtI Sites.doc

APPENDIX A

DOT Standards for Urine Collection Kits

The Collection Kit Contents:

1. Collection Container

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

b. Must have graduated volume markings clearly noting levels of 45 mL and above.

c. Must have a temperature strip providing graduated temperature readings 32-38 ° C / 90-100 ° F, that is affixed or can be affixed at a proper level on the outside of the collection container. Other methodologies (e.g., temperature device built into the wall of the container) are acceptable provided the temperature measurement is accurate and such that there is no potential for contamination of the specimen.

d. Must be individually wrapped in a sealed plastic bag or shrink wrapping; or must have a peelable, sealed lid or other easily visible tamper-evident system.

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

2. Plastic Specimen Bottles

a. Each bottle must be large enough to hold at least 35 mL; or alternatively, they may be two distinct sizes of specimen bottles provided that the bottle designed to hold the primary specimen holds at least 35 mL of urine and the bottle designed to hold the split specimen holds at least 20 mL.

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

c. Must have markings clearly indicating the appropriate levels (30 mL for the primary specimen and 15 mL for the split) of urine that must be poured into the bottles.

d. Must be designed so that the required tamper-evident bottle seals made available on the CCF fit with no damage to the seal when the employee initials it nor with the chance that the seal overlap would conceal printed information.

e. Must be wrapped (with caps) together in a sealed plastic bag or shrink wrapping separate from the collection container; or must be wrapped (with cap) individually in sealed plastic bags or shrink wrapping; or must have peelable, sealed lid or other easily visible tamper-evident system.

f. Plastic material must be leak resistant.

3. Leak-resistant Plastic Bag

a. Must have two sealable compartments or pouches which are leak-resistant; one large enough to hold two specimen bottles and the other large enough to hold the CCF paperwork.

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

4. Absorbent material

Each kit must contain enough absorbent material to absorb the entire contents of both specimen bottles. Absorbent material must be designed to fit inside the leak-resistant plastic bag pouch into which the specimen bottles are placed.

5. Shipping Container

a. Must be designed to adequately protect the specimen bottles from shipment damage in the transport of specimens from the collection site to the laboratory (e.g., standard courier box, small cardboard box, plastic container).

b. May be made available separately at collection sites rather than being part of an actual kit sent to collection sites.

c. A shipping container is not necessary if a laboratory courier hand-delivers the specimen bottles in the plastic leak-proof bags from the collection site to the laboratory.

APPENDIX B

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 type:
    (a) Pre-employment testing: (number)
    (b) Post-accident testing: (number)
    (c) Random testing: (number)
    (d) Reasonable suspicion/cause testing: (number)
    (e) Return-to-duty testing: (number)
    (f) Follow-up testing: (number)
    (g) Type not noted on CCF: (number)

2. Number of specimens reported as
    (a) Negative: (total number)
    (b) Negative-dilute: (number)

3. Number of specimens reported as Rejected for Testing: (total number)
By reason:
    (a) Fatal flaw: (number)
    (b) Uncorrected flaw: (number)

4. Number of specimens reported as Positive: (total number)
   By drug:
    (a) Marijuana Metabolite: (number)
    (b) Cocaine Metabolite: (number)
    (c) Opiates:
        (1) Codeine: (number)
        (2) Morphine: (number)
        (3) 6-AM: (number)
    (d) Phencyclidine: (number)
    (e) Amphetamines: (number)
        (1) Amphetamine: (number)
        (2) Methamphetamine: (number):

5. Adulterated: (number)

6. Substituted: (number)

7. Invalid results: (number)

APPENDIX C – [Reserved]

APPENDIX D

MRO Report Format: Split Specimen Failure to Reconfirm

(To Be Filled Out and Submitted by the MRO)

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 Phone No.: (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 E

SAP Equivalency requirements for Certification Organizations

1. Experience: Minimum requirements are for three years of full-time supervised experience or 6,000 hours of supervised experience as an alcoholism and/or drug abuse counselor. The supervision must be provided by a licensed or certified practitioner. Supervised experience is important if the individual is to be considered a professional in the field of alcohol and drug abuse evaluation and counseling.

2. Education: There exists a requirement of 270 contact hours of education and training in alcoholism and/or drug abuse or related training. These hours can take the form of formal education, in-service training, and professional development courses. Part of any professional counselor's development is participation in formal and non-formal education opportunities within the field.

3. Continuing Education: The certified counselor must receive at least 40 - 60 hours of continuing education units (CEU) during each two year period. These CEUs are important to the counselor's keeping abreast of changes and improvements in the field.

4. Testing: A passing score on a national test is a requirement. The test must accurately measure the application of the knowledge, skills, and abilities possessed by the counselor. The test establishes a national standard that must be met to practice.

5. Testing Validity: The certification examination must be reviewed by an independent authority for validity (examination reliability and relationship to the knowledge, skills, and abilities required by the counseling field). The reliability of the exam is paramount if counselor attributes are to be accurately measured. The examination passing score point must be placed at an appropriate minimal level score as gauged by statistically reliable methodology.

6. Measurable Knowledge Base: The certification process must be based upon measurable knowledge possessed by the applicant and verified through collateral data and testing. That level of knowledge must be of sufficient quantity to ensure a high quality of SAP evaluation and referral services.
7. Measurable Skills Base: The certification process must be based upon measurable skills possessed by the applicant and verified through collateral data and testing. That level of skills must be of sufficient quality to ensure a high quality of SAP evaluation and referral services.

8. Quality Assurance Plan: The certification agency must ensure that a means exists to determine that applicant records are verified as being true by the certification staff. This is an important check to ensure that true information is being accepted by the certifying agency.

9. Code of Ethics: Certified counselors must pledge to adhere to an ethical standard for practice. It must be understood that code violations could result in de-certification. These standards are vital in maintaining the integrity of practitioners. High ethical standards are required to ensure quality of client care and confidentiality of client information as well as to guard against inappropriate referral practices.

10. Re-certification Program: Certification is not just a one-time event. It is a continuing privilege with continuing requirements. Among these are continuing education, continuing state certification, and concomitant adherence to the code of ethics. Re-certification serves as a protector of client interests by removing poor performers from the certified practice.

11. Fifty State Coverage: Certification must be available to qualified counselors in all 50 states

and, therefore, the test must be available to qualified applicants in all 50 states. Because many companies are multi-state operators, consistency in SAP evaluation quality and opportunities is paramount. The test need not be given in all 50 states but should be accessible to candidates from all states.

12. National Commission for Certifying Agencies (NCCA) Accreditation: Having NCCA accreditation is a means of demonstrating to the Department of Transportation that your certification has been reviewed by a panel of impartial experts that have determined that your examination(s) has met stringent and appropriate testing standards.

APPENDIX F

Drug/Alcohol Testing Information that C/TPAs May Transmit to Employers

1. If you are a C/TPA, you may, acting as an intermediary, transmit the information in the following sections of this part to the DER for an employer, if the employer chooses to have you do so. These are the only items that you are permitted to transmit to the employer as an intermediary. The use of C/TPA intermediaries is prohibited in all other cases, such as transmission of laboratory drug test results to MROs, the transmission of medical information from MROs to employers, the transmission of SAP reports to employers, the transmission of positive alcohol test results, and the transmission of medical information from MROs to employers.

2. In every case, you must ensure that, in transmitting the information, you meet all requirements (e.g., concerning confidentiality and timing) that would apply if the party originating the information (e.g., an MRO or collector) sent the information directly to the employer. For example, if you transmit MROs' drug testing results to DERs, you must transmit each drug test result to the DER in compliance with the requirements for MROs set forth in Section 8.21.

Drug testing information:

3.8: Previous two years' test results
4.3: Notice to collectors of contact information for DER
6.1.1: Notification to DER that an employee is a "no show" for a drug test
6.2.5: Notification to DER of a collection under direct observation
6.3.2.6 and .7 and 6.3.3.2 and .3: Notification to DER of a refusal to provide a specimen or an insufficient specimen
6.7.1.9: Transmission of CCF copies to DER (However, MRO copy of CCF must be sent by collector directly to the MRO, not through the C/TPA.)
7.16: Transmission of laboratory statistical report to employer
8.5.4: Report of test results to DER
8.5.6.1: Report to DER of confirmed positive test in stand-down situation
8.13.2: Report to DER of changed test result
8.16.1: Report to DER of dilute specimen
8.17.1.4.2; 8.18.2: Reports to DER that test is cancelled
8.21.2 and .3: Reports of test results to DER
9.9.1, 9.9.2.1, 9.9.3.1, 9.9.4.1 and .2: Reports to DER concerning the reconfirmation of tests
10.1.4: Notice to DER concerning refusals to test
10.2.2.3: Notification to DER of refusal in shy bladder situation
10.2.2.4: Notification to DER of insufficient specimen
10.2.2.5: Transmission of CCF copies to DER (not to MRO)
10.5: Report to DER of cancelled test and direction to DER for additional collection
10.6: Report to DER of cancelled test

Alcohol testing information:

11.3: Notice to BATs and STTs of contact information for DER
13.1.1: Notification to DER that an employee is a “no show" for an alcohol test
13.4.1.2: Transmission of alcohol screening test results only when the test result is less than 0.02
14.3.1.4: Transmission of alcohol confirmation test results only when the test result is less than 0.02
15.2.1.3 and 15.2.2: Notification of insufficient saliva and failure to provide sufficient amount of breath

APPENDIX G

Alcohol Testing Form

U.S. Department of Transportation (DOT)
Alcohol Testing Form

(The instructions for completing this form are *on the back of Copy 3)*

Step 1: TO BE COMPLETED BY ALCOHOL TECHNICIAN

A: Employee Name _____

(Print) (First, M.I., Last)

B: SSN or Employee ID No. _____

C: Employer, Name _____

Street _____

City, ST ZIP _____

DER Name and

Telephone No. _____ _____(___)_____

DER Name **DER Phone Number**

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

Affix Or Print Screening Results Here

Affix With Tamper Evident Tape

STEP 2: TO BE COMPLETED BY EMPLOYEE

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

_____ _____/____/____

Signature of Employee **Date Month Day Year**

Affix Or Print Confirmation Results Here

Affix With Tamper Evident Tape

STEP 3: TO BE COMPLETED BY ALCOHOL TECHNICIAN

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

TECHNICIAN: □BAT □ STT DEVICE: □SALIVA □BREATH* 15-Minute Wait: □Yes □No

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

____ _____ _____ _____ _____ _____

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

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

REMARKS:

_____

_____

_____

_____ _____

Alcohol Technician's Company **Company Street Address**

_____ _____ _____(___)_____

(PRINT) Alcohol Technician's Name (First, M.I., Last) **Company City, State, Zip** **Phone Number**

_____ _____/_____/_____

Signature of Alcohol Technician **Date Month Day Year**

Affix Or Print Additional Results Here

Affix With Tamper Evident Tape

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

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

_____ _____/____/_____

Signature of Employee **Date Month Day Year**

COPY 1 – ORIGINAL – FORWARD TO THE EMPLOYER **OMB N0. 2105-0529** **7MCSA LICY**

8/2006

U.S. Department of Transportation (DOT)
Alcohol Testing Form

(The instructions for completing this form are *on the back of Copy 3)*

Step 1: TO BE COMPLETED BY ALCOHOL TECHNICIAN

A: Employee Name _____

(Print) (First, M.I., Last)

B: SSN or Employee ID No. _____

C: Employer, Name _____

Street _____

City, ST ZIP _____

DER Name and

Telephone No. _____ _____(___)_____

DER Name **DER Phone Number**

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

Affix Or Print Screening Results Here

Affix With Tamper Evident Tape

STEP 2: TO BE COMPLETED BY EMPLOYEE

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

_____ _____/___/___

Signature of Employee **Date Month Day Year**

Affix Or Print Confirmation Results Here

Affix With Tamper Evident Tape

STEP 3: TO BE COMPLETED BY ALCOHOL TECHNICIAN

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

TECHNICIAN: □BAT □ STT DEVICE: □SALIVA □BREATH* 15-Minute Wait: □Yes □No

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

____ _____ _____ _____ _____ _____

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

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

REMARKS:

_____

_____

_____

_____ _____

Alcohol Technician's Company **Company Street Address**

_____ _____ _____(___)_____

(PRINT) Alcohol Technician's Name (First, M.I., Last) **Company City, State, Zip** **Phone Number**

_____ _____/_____/_____

Signature of Alcohol Technician **Date Month Day Year**

Affix Or Print Additional Results Here

Affix With Tamper Evident Tape

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

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

_____ _____/___/_____

Signature of Employee **Date Month Day Year**

COPY 2 - EMPLOYEE RETAINS **OMB N0. 2105-0529**

FMCSA LICY

8/2006

U.S. Department of Transportation (DOT)
Alcohol Testing Form

(The instructions for completing this form are *on the back of Copy 3)*

Step 1: TO BE COMPLETED BY ALCOHOL TECHNICIAN

A: Employee Name _____

(Print) (First, M.I., Last)

B: SSN or Employee ID No. _____

C: Employer, Name _____

Street _____

City, ST ZIP _____

DER Name and

Telephone No. _____ (___)_____

DER Name **DER Phone Number**

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

Affix Or Print Screening Results Here

Affix With Tamper Evident Tape

STEP 2: TO BE COMPLETED BY EMPLOYEE

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

_____ _____/____/____

Signature of Employee **Date Month Day Year**

Affix Or Print Confirmation Results Here

Affix With Tamper Evident Tape

STEP 3: TO BE COMPLETED BY ALCOHOL TECHNICIAN

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

TECHNICIAN: □BAT □ STT DEVICE: □SALIVA □BREATH* 15-Minute Wait: □Yes □No

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

____ _____ _____ _____ _____ _____

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

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

REMARKS:

_____

_____

_____

_____ _____

Alcohol Technician's Company **Company Street Address**

_____ _____ _____(___)_____

(PRINT) Alcohol Technician's Name (First, M.I., Last) **Company City, State, Zip** **Phone Number**

_____ _____/_____/_____

Signature of Alcohol Technician **Date Month Day Year**

Affix Or Print Additional Results Here

Affix With Tamper Evident Tape

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

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

_____ _____/____/_____

Signature of Employee **Date Month Day Year**

COPY 3 – ALCOHOL TECHNICIAN RETAINS **OMB N0. 2105-0529**

FMCSA LICY

8/2006

PAPERWORK REDUCTION ACT NOTICE (as required by 5 CER 1320.21)

Public reporting burden for this collection of information is estimated for each respondent to overage: 1 minute/employee, 4 minutes/Breath Alcohol Technician Individuals may send comments regarding these burden estimates, or any other aspect of this collection of information, including suggestions for reducing the burden, to U.S. Department of Transportation, Drug and alcohol Policy and Compliance. Room 10403, 400 Seventh St., SW, Washington, D.C. 20590 or Office of Management and Budget, Paperwork Reduction Project, Room 3001,725 Seventeenth St., NW, Washington, D.C. 20503

BACK OF PAGES 1 and 2

INSTRUCTIONS FOR COMPLETING THE U.S. DEPARTMENT OF TRANSPORTATION ALCOHOL TESTING FORM

NOTE: Use a ballpoint pen, press hard, and check all copies for legibility.

STEP 1 The Breath Alcohol Technician (BAT) or Screening 'Test Technician (STT) completes the information required in this step. Be sure to print the employee's name and check the box identifying the reason for the test.

NOTE: If the employee refuses to provide SSN or I.D number, be sure to indicate this in the remarks section in STEP 3. Proceed with STEP 2

STEP 2 Instruct the employee to read, sign, and date the employee certification statement in STEP 2.

NOTE: If the employee refuses to sign the certification statement, do not proceed with the alcohol test. Contact the designated employer representative.

STEP 3 The BAT or STT completes the information required in this step and checks the type of device (saliva or breath) being used. After conducting the alcohol screening test, do the following (as appropriate):

Enter the information for the screening test (test number, testing device name, testing device serial number or lot number and expiration date, time of test with any device-dependent activation times, and the results), on the front of the AFT. For a breath - testing device capable of printing, the information may he part of the printed record.

NOTE: Be sure to enter the result of the test exactly as it is indicated on the breath testing device, e.g., 0.00, 0.02, 0.04, etc. Affix the printed information in the space provided, in a tamper-evident manner (e.g., tape), or the device may print the results directly on the ATF. If the results of the screening test are less than 0.02, print, sign your name, and enter today's date in the space provided. The test process is complete

If the results of the screening test are 0.02 or greater, a confirmation test must be administered in accordance with DOT regulations. An EVIDENTIAL. BREATH TESTING device that is capable of printing confirmation test information must be used in conducting this test.

After conducting the alcohol confirmation test, affix the printed information in the space provided, in a tamper-evident manner (e.g., tape), or the device may print the results directly on the ATF. Print, sign your name, and enter the date in the space provided. Go to STEP 4.

STEP 4 If the employee has a breath alcohol confirmation test result of 0.02 or higher, instruct the employee to read, sign, and date the employee certification statement in STEP 4.

NOTE: If the employee refuses to sign the certification statement in STEP 4, be sure to indicate this in the remarks line in STEP 3.

Immediately notify the DER if the employee has a breath alcohol confirmation test result of 0.02 or higher.

Forward Copy 1 to the employer. Give Copy 2 to the employee. Retain Copy 3 for BAT/STT records.

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APPENDIX H

MIS Data Collection Form

U.S. DEPARTMENT OF TRANSPORTATION DRUG AND ALCOHOL TESTING MIS DATA COLLECTION FORM

Calendar Year Covered by this Report: _____ OMB No. 2105-0529

I. Employer:

Company Name:_____

Doing Business As (DBA) Name (if applicable):_____

Address:_____ E-mail: _____

Name of Certifying Official: _____ Signature: _____

Telephone: (_____)_____ Date Certified: _____

Prepared by (if different): _____ Telephone: (_____)_____

C/TPA Name and Telephone (if applicable): _____ (_____)_____

Check the DOT agency for which you are reporting MIS data; and complete the information on that same line as appropriate:

___ FMCSA – Motor Carrier: DOT #: _____ Owner-operator: (circle one) YES or NO Exempt (Circle One) YES or NO

___ FAA – Aviation: Certificate # (if applicable): _____ Plan / Registration # (if applicable):_____

___ RSPA – Pipeline: (Check) Gas Gathering__ Gas Transmission__ Gas Distribution__ Transport Hazardous Liquids__ Transport Carbon Dioxide__

___ FRA – Railroad: Total Number of observed/documented Part 219 "Rule G" Observations for covered employees: _____

___ USCG – Maritime: Vessel ID # (USCG- or State-Issued): _____ (If more than one vessel, list separately.)

___ FTA – Transit

II. Covered Employees: **(A) Enter Total Number Safety-Sensitive Employees In All Employee Categories:**

(B) Enter Total Number of Employee Categories:

(C)

Employee Category	Total Number of Employees in this Category

If you have multiple employee categories, complete Sections I and II (A) & (B). Take that filled-in form and make one copy for each employee category and complete Sections II (C), III, and IV for each separate employee category.

III. Drug Testing Data:

	1	2	3	4	5	6	7	8	9	10	11	12	13
									Refusal Results				
Type of Test	Total Number Of Test Results [Should equal the sum of Columns 2, 3, 9, 10, 11, and 12]	Verified Negative Results	Verified Positive Results ~ For One Or More Drugs	Positive For Marijuana	Positive For Cocaine	Positive For PCP	Positive For Opiates	Positive For Amphetamines	Adulterated	Substituted	"Shy Bladder" ~ With No Medical Explanation	Other Refusals To Submit To Testing	Cancelled Results
Pre-Employment													
Random													
Post-Accident													
Reasonable Susp./Cause													
Return-to-Duty													
Follow-Up													
TOTAL													

IV. Alcohol Testing Data:

	1	2	3	4	5	6	7	8	9
							Refusal Results		
Type of Test	Total Number Of Screening Test Results [Should equal the sum of Columns 2, 3, 7, and 8]	Screening Tests With Results Below 0.02	Screening Tests With Results 0.02 Or Greater	Number Of Confirmation Tests Results	Confirmation Tests With Results 0.02 Through 0.039	Confirmation Tests With Results 0.04 Or Greater	"Shy Lung" ~ With No Medical Explanation	Other Refusals To Submit To Testing	Cancelled Results
Pre-Employment									
Random									
Post-Accident									
Reasonable Susp./Cause									
Return-to-Duty									
Follow-Up									
TOTAL									

PAPERWORK REDUCTION ACT NOTICE (as required by 5 CFR 1320.21)

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 2105-0529. The Department of Transportation estimates that the average burden for this report form is 1.5 hours. You may send comments regarding this burden estimate or any suggestions for reducing the burden to: U.S. Department of Transportation, Office of Drug and Alcohol Policy and Compliance, Room 10403, 400 Seventh Street, SW, Washington, D.C. 20590; OR Office of Management and Budget, Paperwork Reduction Project, 725 Seventeenth Street, NW, Washington, D.C. 20503.

Title 18, USC Section 1001, makes it a criminal offense subject to a maximum fine of $10,000, or imprisonment for not more than 5 years, or both, to knowingly and willfully make or cause to be made any false or fraudulent statements of representations in any matter within the jurisdiction of any agency of the United States.

Note: DOT will publish a new form changing RSPA to PHMSA; the new form will be available on their Web site.

APPENDIX I

MIS Instructions

U.S. DEPARTMENT OF TRANSPORTATION
DRUG AND ALCOHOL TESTING MIS DATA COLLECTION FORM
INSTRUCTION SHEET

This Management Information System (MIS) form is made-up of four sections: employer information; covered employees (i.e., employees performing DOT regulated safety-sensitive duties) information; drug testing data; and alcohol testing data. The employer information needs only to be provided once per submission. However, you must submit a separate page of data for each employee category for which you report testing data. If you are preparing reports for more than one DOT agency then you must submit DOT agency-specific forms.

Please type or print entries legibly in black ink.

TIP *Read the entire instructions before starting. Please note that USCG-regulated employers do not report alcohol test results on the MIS form.*

Calendar Year Covered by this Report: Enter the appropriate year.

Section I. Employer

1. Enter your company's name, include when applicable, your "doing business as" name; current address, city, state, and zip code; and an e-mail address, if available.
2. Enter the printed name, signature, and complete telephone number of the company official certifying the accuracy of the report and the date that person certified the report as complete.
3. If someone other than the certifying official completed the MIS form, enter that person's name and phone number on the appropriate lines provided.
4. If a Consortium/Third Party Administrator (C/TPA) performs administrative services for your drug and alcohol program operation, enter its name and phone number on the appropriate lines provided.
5. DOT Agency Information: Check the box next to the DOT agency for which you are completing this MIS form. Again, if you are submitting to multiple DOT agencies, you must use separate forms for each DOT agency.

a. If you are completing the form for FMCSA, enter your FMCSA DOT Number, as appropriate. In addition, you must indicate whether you are an owner-operator (i.e., an employer who employs only himself or herself as a driver) and whether you are exempt from providing MIS data. Exemptions are noted in the FMCSA regulation at 382.103(d).
b. If you are completing the form for FAA, enter your FAA Certificate Number and FAA Antidrug Plan / Registration Number, when applicable.
c. If you are completing the form for PHMSA, check the additional box(s) indicating your type of operation.
d. If you are completing the form for FRA, enter the number of observed/documented Part 219 "Rule G" Observations for covered employees.
e. If you are submitting the form for USCG, enter the vessel ID number. If there is more than one number, enter the numbers separately.

Section II. Covered Employees

1. In Box II-(A), enter the total number of covered employees (i.e., employees performing DOT regulated safety-sensitive duties) who work for your company. Then enter, in Box II-(B), the total number of employee categories that number represents. If you have employees, some of whom perform duties under one DOT agency and others of whom perform duties under another DOT agency, enter only the number of those employees performing duties under the DOT agency for whom you are submitting the form. If you have covered employees who perform multi-DOT agency functions (e.g., an employee drives a commercial motor vehicle and performs pipeline maintenance duties for you), count the employee only on the MIS report for the DOT agency regulating more than 50 percent of the employee's safety sensitive function.

[Example: If you are submitting the information for the FRA and you have 2000 covered employees performing duties in all FRA-covered service categories you would enter "2000" in the first box (II-A) and *"5"* in the second box (II-B), because FRA has five safety-sensitive employee categories and you have employees in all of these groups. If you have 1000 employees performing safety-sensitive duties in three FRA-covered service categories (e.g., engine service, train service, and dispatcher/operation), you would enter "1000" in the first box (II-A) and "3" in the second box (II-B).]

TIP *To calculate the total number of covered employees, add the total number of covered employees eligible for testing during each random testing selection period for the year and divide that total by the number of random testing periods. (However, no company will need to factor the average number of employees more often than once per month). For instance, a company conducting random testing quarterly needs to add the total of covered employees they had in the random pool when each selection was made; then divide this number by 4 to obtain the yearly average number of covered employees. It is extremely important that you place all eligible employees into these random pools. [As an example, if Company A had 1500 employees in the first quarter random pool, 2250 in the second quarter, 2750 in the third quarter, and 1500 in the fourth quarter; 1500+ 2250 + 2750 + 1500 = 8000; 8000/4 = 2000; the total number of covered employees for the year would be reported as, "2000."*

If you conduct random selections more often than once per month (e.g., you select daily, weekly, bi-weekly), you do not need to compute this total number of covered employees rate more than on a once per month basis. Therefore, employers need not compute the covered employees rate more than 12 times per year.

2. If you are reporting multiple employee categories, enter the specific employee category in box II-C; and provide the number of employees performing safety-sensitive duties in that specific category.

[Example: You are submitting data to the FTA and you have 2000 covered employees. You have 1750 personnel performing revenue vehicle operation and the remaining 250 are performing revenue vehicle and equipment maintenance. When you provide vehicle operation information, you would enter "Revenue Vehicle Operation" in the first II-C box and "1750" in the second II-C box. When you provide data on the maintenance personnel, you would enter "Revenue Vehicle and Equipment Maintenance" in the first II-C box and "250" in the second II-C box.]

TIP *A separate form for each employee category must be submitted. You may do this by filling out a single MIS form through Section II-B and then make one copy for each additional employee*

category you are reporting. [For instance, if you are submitting the MIS form for the FMCSA, you need only submit one form for all FMCSA covered employees working for you —your only category of employees is "driver." If you are reporting testing data to the FAA and you employ only flight crewmembers, flight attendants, and aircraft maintenance workers, you need to complete one form each for category –three forms in all. If you are reporting to FAA and have all FAA categories of covered employees, you must submit eight forms.]

Here is a full listing of covered-employee categories:

***FMCSA** (one category): Driver*
***FAA** (eight categories): Flight Crewmember; Flight Attendant; Flight Instructor; Aircraft Dispatcher; Aircraft Maintenance; Ground Security Coordinator; Aviation Screener; Air Traffic Controller*
***PHMSA** (one category): Operation/Maintenance/Emergency Response*
***FRA** (five categories): Engine Service; Train Service; Dispatcher/Operation; Signal Service; Other [Includes yardmasters, hostlers (non-engineer craft), bridge tenders; switch tenders, and other miscellaneous employees performing 49 CFR 228.5 (c) defined covered service.]*
***USCG** (one category): Crewmember*
***FTA** (five categories): Revenue Vehicle Operation; Revenue Vehicle and Equipment Maintenance; Revenue Vehicle Control/Dispatch; CDL/Non-Revenue Vehicle, Armed Security Personnel*

Section III. Drug Testing Data

This section summarizes the drug testing results for all covered employees (to include applicants). The table in this section requires drug test data by test type and by result. The categories of test types are: Pre-Employment; Random; Post-Accident; Reasonable Suspicion / Reasonable Cause; Return-to-Duty, and Follow-Up.

The categories of type of results are: Total Number of Test Results [excluding cancelled tests and blind specimens]; Verified Negative; Verified Positive; Positive for Marijuana; Positive for Cocaine; Positive for PCP; Positive for Opiates; Positive for Amphetamines; Refusals due to Adulterated, Substituted, "Shy Bladder" with No Medical Explanation, and Other Refusals to Submit to Testing; and Cancelled Results.

***TIP** Do not enter data on blind specimens submitted to laboratories. Be sure to enter all pre-employment testing data regardless of whether an applicant was hired or not. You do not need to separate reasonable suspicion and reasonable cause drug testing data on the MIS form. [Therefore, if you conducted only reasonable suspicion drug testing (i.e., FMCSA and FTA), enter that data; if you conducted only reasonable cause drug testing (i.e., FAA, PHMSA, and USCG,); or if you conducted both under FRA drug testing rules, simply enter the data with no differentiation.] For USCG, enter any "Serious Marine Incident" testing in the Post-Accident row. For FRA, do not enter post accident data (the FRA does not collect this data on the MIS form). Finally, you may leave blank any row or column in which there were no results, or you may enter "0" (zero) instead. Please note that cancelled tests are not included in the "total number of test results" column.*

Section III, Column 1. Total Number of Test Results This column requires a count of the total number of test results in each testing category during the entire reporting year. Count the number of test results as the number of testing events resulting in negative, positive, and refusal results.

Do not count cancelled tests and blind specimens in this total.

[Example: A company that conducted fifty pre-employment tests would enter "50" on the Pre-Employment row. If it conducted one hundred random tests, "100" would be entered on the Random row. If that company did no post-accident, reasonable suspicion, reasonable cause, return-to-duty, or follow-up tests, those categories will be left blank or zeros entered.]

Section III, Column 2. Verified Negative Results This column requires a count of the number of tests in each testing category that the Medical Review Officer (MRO) reported as negative. Do not count a negative-dilute result if, subsequently, the employee underwent a second collection; the second test is the test of record.

[Example: If forty-seven of the company's fifty pre-employment tests were reported negative, "47" would be entered in Column 2 on the Pre-Employment row. If ninety of the company's one hundred random test results were reported negative, "90" would be entered in Column 2 on the Random row. Because the company did no other testing, those other categories would be left blank or zeros entered.]

Section III, Column 3. Verified Positive Results For One Or More Drugs This column requires a count of the number of tests in each testing category that the MRO reported as positive for one or more drugs. When the MRO reports a test positive for two drugs, it would count as one positive test.

[Example: If one of the fifty pre-employment tests was positive for two drugs, "1" would be entered in Column 3 on the Pre-Employment row. If four of the company's one hundred random test results were reported positive (three for one drug and one for two drugs), "4" would be entered in Column 3 on the Random row.]

Section III, Columns 4 through 8. Positive (for specific drugs) These columns require entry of the by-drug data for which specimens were reported positive by the MRO.

[Example: The pre-employment positive test reported by the MRO was positive for marijuana, "1" would be entered in Column 4 on the Pre-Employment row. If three of the four positive results for random testing were reported by the MRO to be positive for marijuana, "3" would be entered in Column 4 on the Random row. If one of the four positive results for random testing was reported positive for both PCP and opiates, "1" would be entered in Column 6 on the Random row and "1" would be entered in Column 7 of the Random row.]

TIP *Column 1 should equal the sum of Columns 2, 3, 9, 10, 11, and 12. Remember you have not counted specimen results that were ultimately cancelled or were from blind specimens. So, Column 1 = Column 2 + Column 3 + Column 9 + Column 10 + Column 11 + Column 12. Certainly, double check your records to determine if your actual results count is reflective of all negative, positive, and refusal counts.*

An MRO may report that a specimen is positive for more than one drug. When that happens, to use the company example above (i.e., one random test was positive for both PCP and opiates), the positive results should be recorded in the appropriate columns - PCP and opiates in this case. There is no expectation for Columns 4 through 8 numbers to add up to the numbers in Column 3 when you report multiple positives.

Section III, Columns 9 through 12. Refusal Results The refusal section is divided into four refusal groups - they are: Adulterated; Substituted; "Shy Bladder" With No Medical Explanation; and Other Refusals To Submit to Testing. The MRO reports two of these refusal types, adulterated and substituted specimen results, because of laboratory test findings.

When an individual does not provide enough urine at the collection site, the MRO conducts or causes to have conducted a medical evaluation to determine if there exists a medical reason for the person's inability to provide the appropriate amount of urine. If there is no medical reason to support the inability, the MRO reports the result to the employer as a refusal to test: Refusals of this type are reported in the "Shy Bladder" With No Medical Explanation category.

Finally, additional reasons exist for a test to be considered a refusal. Some examples are: the employee fails to report to the collection site as directed by the employer; the employee leaves the collection site without permission; the employee fails to empty his or her pockets at the collection site; the employee refuses to have a required shy bladder evaluation. Again, these are only four examples: there are more.

Section III, Column 9. Adulterated This column requires the count of the number of tests reported by the MRO as refusals because the specimens were adulterated.

[Example: If one of the fifty pre-employment tests was adulterated, "1" would be entered in Column 9 of the Pre-Employment row.]

Section III, Column 10. Substituted This column requires the count of the number of tests reported by the MRO as refusals because the specimens were substituted.

[Example: If one of the 100 random tests was substituted, "1" would be entered in Column 10 of the Random row.]

Section III, Column 11. "Shy Bladder" With No Medical Explanation This column requires the count of the number of tests reported by the MRO as being a refusal because there was no legitimate medical reason for an insufficient amount of urine.

[Example: If one of the 100 random tests was a refusal because of shy bladder, "1" would be entered in Column 11 of the Random row.]

Section III, Column 12. Other Refusals To Submit To Testing This column requires the count of refusals other than those already entered in Columns 9 through 11.

[Example: If the company entered "100," as the number of random specimens collected, however it had five employees who refused to be tested without submitting specimens: two did not show up at the collection site as directed; one refused to empty his pockets at the collection site; and two left the collection site rather than submit to a required directly observed collection. Because of these five refusal events, "5" would be entered in Column 12 of the Random row.]

TIP *Even though some testing events result in a refusal in which no urine was collected and sent to the laboratory, a "refusal" is still a final test result. Therefore, your overall numbers for test results (in Column 1) will equal the total number of negative tests (Column 2); positives (Column 3); and refusals (Columns 9, 10, 11, and 12). Do not worry that no urine was processed at the laboratory for some refusals; all refusals are counted as a testing event for MIS purposes and for*

establishing random rates.

Section III Column 13. Cancelled Tests This column requires a count of the number of tests in each testing category that the MRO reported as cancelled. You must not count any cancelled tests in Column 1 or in any other column. For instance, you must not count a positive result (in Column 3) if it had ultimately been cancelled for any reason (e.g., specimen was initially reported positive, but the split failed to reconfirm).

[Example: If a pre-employment test was reported cancelled, "1" would be entered in Column 13 on the Pre-Employment row. If three of the company's random test results were reported cancelled, "3" would be entered in Column 13 on the Random row.]

TOTAL Line. Columns 1 through 13 This line requires you to add the numbers in each column and provide the totals.

Section IV. Alcohol Testing Data

This section summarizes the alcohol testing conducted for all covered employees (to include applicants). The table in this section requires alcohol test data by test type and by result. The categories of test types are: Pre-Employment; Random; Post-Accident; Reasonable Suspicion/ Reasonable Cause; Return-to-Duty, and Follow-Up.

The categories of results are: Number of Screening Test Results; Screening Tests with Results Below 0.02; Screening Tests with Results 0.02 Or Greater; Number of Confirmation Test Results; Confirmation Tests with Results 0.02 through 0.039; Confirmation Tests with Results 0.04 Or Greater; Refusals due to "Shy Lung" with No Medical Explanation; Other Refusals to Submit to Testing; and Cancelled Results.

TIP *Be sure to enter all pre-employment testing data regardless of whether an applicant was hired or not. Of course, for most employers, pre-employment alcohol testing is optional, so you may not have conducted this type of testing. You do not need to separate "reasonable suspicion" and "reasonable cause" alcohol testing data on the MIS form. [Therefore, if you conducted only reasonable suspicion alcohol testing (i.e., FMCSA, FAA, FTA, and PHMSA), enter that data; if you conducted both reasonable suspicion and reasonable cause alcohol testing (i.e., FRA), simply enter the data with no differentiation.] PHMSA does not authorize "random" testing for alcohol. Finally, you may leave blank any row or column in which there were no results, or you may enter "0", (zero) instead. Please note that USCG-regulated employers do not report alcohol test results on the MIS form: Do not fill-out Section IV if you are a USCG-regulated employer.*

Section IV, Column 1. Total Number of Screening Test Results This column requires a count of the total number of screening test results in each testing category during the entire reporting year. Count the number of screening tests as the number of screening test events with final screening results of below 0.02, of 0.02 through 0.039, of 0.04 or greater, and all refusals. Do not count cancelled tests in this total.

[Example: A company that conducted twenty pre-employment tests would enter "20" on the Pre-Employment row. If it conducted fifty random tests, *"50"* would be entered. If that company did no post-accident, reasonable suspicion, reasonable cause, return-to-duty, or follow-up tests, those categories will be left blank or zeros entered.]

Section IV, Column 2. Screening Tests With Results Below 0.02 This column requires a count of the number of tests in each testing category that the BAT or STT reported as being below 0.02 on the screening test.

[Example: If seventeen of the company's twenty pre-employment screening tests were reported as being below 0.02, "17" would be entered in Column 2 on the Pre-Employment row. If forty-four of the company's fifty random screening test results were reported as being below 0.02, "44" would be entered in Column 2 on the Random row. Because the company did no other testing, those other categories would be left blank or zeros entered.]

Section IV, Column 3. Screening Tests With Results 0.02 Or Greater This column requires a count of the number of screening tests in each testing category that BAT or STT reported as being 0.02 or greater on the screening test.

[Example: If one of the twenty pre-employment tests was reported as being 0.02 or greater, "1" would be entered in Column 3 on the Pre-Employment row. If four of the company's fifty random test results were reported as being 0.02 or greater, "4" would be entered in Column 3 on the Random row.]

Section IV, Column 4. Number of Confirmation Test Results This column requires entry of the number of confirmation tests that were conducted by a BAT as a result of the screening tests that were found to be 0.02 or greater. In effect, all screening tests of 0.02 or greater should have resulted in confirmation tests. Ideally the number of tests in Column 3 and Column 4 should be the same. However, we know that this required confirmation test sometimes does not occur. In any case, the number of confirmation tests that were actually performed should be entered in Column 4.

[Example: If the one pre-employment screening test reported as 0.02 or greater had a subsequent confirmation test performed by a BAT, "1," would be entered in Column 4 on the Pre-Employment row. If three of the four random screening tests that were found to be 0.02 or greater had a subsequent confirmation test performed by a BAT, "3" would be entered in Column 4 on the Random row.]

Section IV, Column 5. Confirmation Tests With Results 0.02 Through 0.039 This column requires entry of the number of confirmation tests that were conducted by a BAT that led to results that were 0.02 through 0.039.

[Example: If the one pre-employment confirmation test yielded a result of 0.042, Column *5* of the Pre-Employment row would be left blank or zeros entered. If two of the random confirmation tests yielded results of 0.03 and 0.032, "2" would be entered in Column *5* of the Random row.]

Section IV, Column 6. Confirmation Tests With Results 0.04 Or Greater This column requires entry of the number of confirmation tests that were conducted by a BAT that led to results that were 0.04 or greater.

[Example: Because the one pre-employment confirmation test yielded a result of 0.042, "1" would be entered in Column 6 of the Pre-Employment row. If one of the random confirmation tests yielded a result of 0.04, "1," would be entered in Column 6 of the Random row.]

TIP *– Column 1 should equal the sum of Columns 2, 3, 7, and 8. The number of screening tests results should reflect the number of screening tests you have no matter the result (below 0.02 or at or above 0.02, plus refusals to test), unless of course, the tests were ultimately cancelled. So, Column 1 = Column 2 + Column 3 + Column 7 + Column 8. Certainly, double check your records to determine if your actual screening results count is reflective of all these counts. There is no need to record MIS confirmation tests results below 0.02. That is why we have no column for it on the form. [If the random test that screened 0.02 went to a confirmation test, and that confirmation test yielded a result below 0.02, there is no place for that confirmed result to be entered]. We assume that if a confirmation test was completed but not listed in either Column 5 or Column 6, the result was below 0.02. In addition if the confirmation test ended up being cancelled, it should not have been included in Columns 1, 3, or 4 in the first place.*

Section IV, Columns 7 and 8. Refusal Results The refusal section is divided into two refusal groups they are: Shy Lung With No Medical Explanation; and Other Refusals To Submit to Testing. When an individual does not provide enough breath at the test site, the company requires the employee to have a medical evaluation to determine if there exists a medical reason for the person's inability to provide the appropriate amount of breath. If there is no medical reason to support the inability as reported by the examining physician, the employer calls the result a refusal to test. Refusals of this type are reported in the "Shy Lung With No Medical Explanation" category.

Finally, additional reasons exist for a test to be considered a refusal. Some examples are: the employee fails to report to the test site as directed by the employer; the employee leaves the test site without permission; the employee fails to sign the certification at Step 2 of the ATF; the employee refuses to have a required shy lung evaluation. Again, these are only four examples; there are more.

Section IV, Column 7. "Shy Lung" With No Medical Explanation This column requires the count of the number of tests in which there is no medical reason to support the employee's inability to provide an adequate breath as reported by the examining physician; subsequently, the employer called the result a refusal to test.

[Example: If one of the 50 random tests was a refusal because of shy lung, "1" would be entered in Column 7 of the Random row.]

Section IV, Column 8. Other Refusals To Submit To Testing This column requires the count of refusals other than those already entered in Column 7.

[Example: The company entered "50" as the number of random specimens collected, however it had one employee who did not show up at the testing site as directed. Because of this one refusal event, "1" would be entered in Column 8 of the Random row.]

TIP *– Even though some testing events result in a refusal in which no breath (or saliva) was tested, there is an expectation that your overall numbers for screening tests (in Column 1) will equal the total number of screening tests with results below 0.02 (Column 2); screening tests with results 0.02 or greater (Column 3); and refusals (Columns 7 and 8). Do not worry that no breath (or saliva) was tested for some refusals; all refusals are counted as a screening test event for MIS purposes and for establishing random rates.*

Section IV, Column 9. Cancelled Tests This column requires a count of the number of tests in

each testing category that the BAT or STT reported as cancelled. Do not count any cancelled tests in Column 1 or in any other column other than Column 9. For instance, you must not count a 0.04 screening result or confirmation result in any column, other than Column 9, if the test was ultimately cancelled for some reason (e.g., a required air blank was not performed).

[Example: If a pre-employment test was reported cancelled, "1" would be entered in Column 9 on the Pre-Employment row. If three of the company's random test results were reported cancelled, "3" would be entered in Column 13 on the Random row.]

TOTAL Line. Columns 1 through 9 This line requires you to add the numbers in each column and provide the totals.

APPENDIX J

NHTSA Conforming Products List of Alcohol Screening Devices

September 19, 2005

Manufacturer	Device(s)
AK Solutions, Inc., Palisades Park, NJ [1]	Alcoscan AL-2500. AlcoChecker. AlcoKey. EAlcoMate. AlcoMate Pro. Alcoscan AL-5000. Alcoscan AL-6000.
Alco Check International, Hudsonville, MI	Alco Check 3000 D.O.T. Alco Check 9000.
Chematics, Inc., North Webster, IN	ALCO-SCREEN 02TM. [2]
Guth Laboratories, Inc., Harrisburg, PA	Alco Tector Mark X. Mark X Alcohol Checker. Alcotector WAT89EC-1.
Han International Co., Ltd., Seoul, Korea [3]	A.B.I. (Alcohol Breath Indicator).
OraSure Technologies, Inc., Bethlehem, PA	Q.E.D. A150 Saliva Alcohol Test.
PAS Systems International, Inc., Fredericksburg, VA	PAS Vr.
Q3 Innovations, Inc., Independence, IA [4]	Alcohawk[supreg] Precision. Alcohawk[supreg] Elite. Alcohawk[supreg] ABI. Alcohawk[supreg] PRO.
Repco Marketing, Inc., Raleigh, NC	Alco Tec III.
Seju Co. of Taejeon, Korea	Safe-Slim.
Sound Off, Inc., Hudsonville, MI	Digitox D.O.T.
Varian, Inc., Lake Forest, CA	Q.E.D. A150 Saliva Alcohol Test. [5]

The devices manufactured by Chematics, Inc., OraSure Technologies, Inc., and Varian, Inc.are all single-use, disposable saliva alcohol test devices. All of the other devices listed on the CPL are electronic breath testers. The device called the ``Alcotector WAT89EC-1" manufactured by Guth Laboratories, Inc. and the PAS Vr device manufactured by PAS Systems International, Inc. use fuel-cell sensors, whereas all other electronic devices listed on the CPL use semi-conductor sensors.

[1] The AlcoMate was manufactured by Han International of Seoul, Korea, but marketed and sold in the U.S. by AK Solutions.

[2] While the ALCO-SCREEN 02TM saliva-alcohol screening device manufactured by Chematics, Inc. passed the requirements of the Model Specifications when tested at 40° C (104° F), the manufacturer has indicated that the device cannot exceed storage temperatures of 27° (80° F). Instructions to this effect are stated on all packaging accompanying the device. Accordingly, the device should not be stored at temperatures above 27° C (80° F). If the device is stored at or below 27° C (80° F) and used at higher temperatures (i.e., within a minute), the device meets the Model Specifications and the results persist for 10 - 15 minutes. If the device is stored at or below 27° C (80° F) and equilibrated at 40° C (104° F) for an hour prior to sample application, the device fails to meet the Model Specifications. Storage at temperatures above 27° C (80° F), for even brief periods of time, may result in false negative readings.

[3] Han International does not market or sell devices directly in the U. S. market. Other devices manufactured by Han International are listed under AK Solutions, Inc. and Q-3 Innovations, Inc.

[4] The AlcoHawk ABI is the same device as that listed under Han International as the ``ABI'' and is manufactured for Q-3 Innovations by Han International. The Alcohawk PRO is the same device as the AlcoMate marketed and sold by AK Solutions, and also manufactured by Han International.

[5] While this device passed all of the requirements of the Model Specifications, readings should be taken only after the time specified by the manufacturer. For valid readings, the user should follow the manufacturer's instructions. Readings should be taken one (1) minute after a sample is introduced at or above 30° C (86° F); readings should be taken after two (2) minutes at 18° C - 29° C (64.4° - 84.2° F); and readings should be taken after five (5) minutes when testing at temperatures at or below 17° C (62.6° F). If the reading is taken before five (5) minutes has elapsed under the cold conditions, the user is likely to obtain a reading that underestimates the actual saliva-alcohol level.

APPENDIX K

NHTSA Conforming Products List of Evidential Breath Measurement Devices

(Note: Only those devices listed without an asterisk (*) are authorized for use in confirmation testing in the DOT program.)

Manufacturer and model	Mobile	Non-mobile
Alcohol Countermeasure Systems Corp. Mississauga, Ontario, Canada:		
Alert J3AD*	X	X
Alert J4X.ec	X	X
PBA3000C	X	X
BAC Systems, Inc., Ontario, Canada: Breath Analysis Computer*	X	X
CAMEC Ltd., North Shields, Tyne and Ware England:		
IR Breath Analyzer*	X	X
CMI, Inc., Owensboro, KY:		
Intoxilyzer Model:		
200	X	X
200D	X	X
300	X	X
400	X	X
400PA	X	X
1400	X	X
4011*	X	X
4011A*	X	X
4011AS*	X	X
4011AS-A*	X	X
4011AS-AQ*	X	X
4011 AW*	X	X
4011A27-10100*	X	X
4011A27-10100 with filter*	X	X
5000	X	X
5000 (w/Cal. Vapor Re-Circ.)	X	X
5000 (w/\3/8\ ID Hose option)	X	X
5000CD	X	X
5000CD/FG5	X	X
5000EN	X	X
5000 (CAL DOJ)	X	X
5000VA	X	X
8000	X	X
PAC 1200*	X	X
S-D2	X	X
S-D5	X	X

Draeger Safety, Inc., Durango, CO:		
Alcotest Model:		
6510	X	X
6810	X	X
7010*	X	X
7110*	X	X
7110 MKIII	X	X
7110 MKIII-C	X	X
7410	X	X
7410 Plus	X	X
Breathalyzer Model:		
900*	X	X
900A*	X	X
900BG*	X	X
7410	X	X
7410-II	X	X
Gall's Inc., Lexington, KY: Alcohol Detection System--A.D.S. 500 …	X	X
Guth Laboratories, Inc., Harrisburg, PA		
Alcotector BAC-100	X	X
Alvotector C2H5OH	X	X
Intoximeters, Inc., St. Louis, MO:		
Photo Electric Intoximeter*	…..	X
GC Intoximeter MK II*	X	X
GC Intoximeter MK IV*	X	X
Auto Intoximeter*	X	X
Intoximeter Model:		
3000*	X	X
3000 (rev B1)*	X	X
3000 (rev B2)*	X	X
3000 (rev B2A)*	X	X
3000 (rev B2A) w/FM option*	X	X
3000 (Fuel Cell)*	X	X
3000 D*	X	X
3000 DFC*	X	X
Alcomonitor	…..	X
Alcomonitor CC	X	X
Alco-Sensor III	X	X
Alco-Sensor III (Enhanced with Serial Numbers above 1,200,000)	X	X
Alco-Sensor IV	X	X
Alco-Sensor IV-XL	X	X
Alco-Sensor AZ	X	X
Alco-Sensor FST	X	X
RBT-AZ	X	X
RBT III	X	X
RBT III-A	X	X
RBT IV	X	X
RBT IV with CEM (cell enhancement module)	X	X
Intox EC/IR	X	X

Intox EC/IR II	X	X
Portable Intox EC/IR	X	X
Komyo Kitagawa, Kogyo, K.K.:		
Alcolyzer DPA-2*	X	X
Breath Alcohol Meter PAM 101B*	X	X
Lifeloc Technologies, Inc., (formerly Lifeloc, Inc.), Wheat Ridge, CO:		
PBA 3000B	X	X
PBA 3000-P*	X	X
PBA 3000C	X	X
Alcohol Data Sensor	X	X
Phoenix	X	X
EV 30	X	X
FC 10	X	X
FC 20	X	X
Lion Laboratories, Ltd., Cardiff, Wales, UK:		
Alcolmeter Model:		
300	X	X
400	X	X
SD-2*	X	X
EBA*	X	X
Intoxilyzer Model:		
200	X	X
200D	X	X
1400	X	X
5000 CD/FG5	X	X
5000 EN	X	X
Luckey Laboratories, San Bernadino, CA:		
Alco-Analyzer Model:		
1000*	…..	X
2000*	…..	X
National Draeger, Inc., Durango, CO:		
Alcotest Model:		
7010*	X	X
7110*	X	X
7110 MKIII	X	X
7110 MKIII-C	X	X
7410	X	X
7410 Plus	X	X
Breathalyzer Model:		
900*	X	X
900A*	X	X
900BG*	X	X
7410	X	X
7410-II	X	X

National Patent Analytical Systems, Inc., Mansfield, OH:		
BAC DataMaster (with or without the Delta-1accessory).....	X	X
BAC Verifier DataMaster (with or without the Delta-1 accessory).....	X	X
DataMaster cdm (with or without the Delta-1accessory).....	X	X
DataMaster DMT…….	X	X
Omicron Systems, Palo Alto, CA:		
Intoxilyzer Model:		
4011*.....……	X	X
4011AW*.....……	X	X
Plus 4 Engineering, Minturn, CO: 5000 Plus4*.... ……	X	X
Seres, Paris, France:		
Alco Master.....……	X	X
Alcopro.....……	X	X
Siemans-Allis, Cherry Hill, NJ:		
Alcomat*.....……	X	X
Alcomat F*.....……...	X	X
Smith and Wesson Electronics, Springfield, MA:		
Breathalyzer Model:		
900*.....……	X	X
900A*.....……..	X	X
1000*.....……	X	X
2000*.....……	X	X
2000 (non-Humidity Sensor)*.....……	X	X
Sound-Off, Inc., Hudsonville, MI:		
AlcoData.....……..	X	X
Seres Alco Master.....……	X	X
Seres Alcopro.....……..	X	X
Stephenson Corp.: Breathalyzer 900*.....……	X	X
U.S. Alcohol Testing, Inc./Protection Devices, Inc., Rancho Cucamonga, CA:		
Alco-Analyzer 1000.....……	…..	X
Alco-Analyzer 2000.....……	…..	X
Alco-Analyzer 2100.....……	X	X
Verax Systems, Inc., Fairport, NY:		
BAC Verifier*.....…….	X	X
BAC Verifier Datamaster.....…….	X	X
BAC Verifier Datamaster II*.....……	X	X

*Instruments marked with an asterisk (*) meet the Model Specifications detailed in 49 FR 48854 (December 14, 1984) (i.e., instruments tested at 0.000, 0.050, 0.101, and 0.151 BAC). Instruments not marked with an asterisk meet the Model Specifications detailed in 58 FR 48705 (September 17, 1993), and were tested at BACs = 0.000, 0.020, 0.040, 0.080, and 0.160. All instruments that meet the Model Specifications currently in effect (dated September 17, 1993) also meet the Model Specifications for Screening Devices to Measure Alcohol in Bodily Fluids.