Memorandum

MIAMI-DADE COUNTY

Date: November 15, 2011

To: Honorable Chairman Joe A. Martinez
and Members, Board of County Commissioners

Agenda Item No. 8(F)(16)

From: Carlos A. Gimenez
Mayor

Subject: Recommendation to Approve an Intergovernmental Agreement with Jackson Health System for Employee Testing & Medical Assessment Services

RECOMMENDATION

It is recommended that the Board of County Commissioners (Board) approve an intergovernmental agreement (Agreement) with Jackson Health System (JHS) to provide employee testing and medical assessment services for Miami-Dade County. The current contract extension for these services with Mt. Sinai Medical Center of Florida, Inc (Mt. Sinai) expires on December 17, 2011.

This recommendation supersedes the County Manager's recommendation for award to Mt. Sinai dated June 7, 2011, which is an accompanying item on this same agenda. Furthermore, I recommend the rejection of all proposals received for the same services under RFP 737, *Employee Testing and Medical Assessment Services*.

The recommended Agreement with JHS provides the same level of services with lower rates than the current contract with Mt. Sinai for medical assessments and testing. The JHS proposal provides an across the board reduction of service rates that range from eight percent to 23 percent as does Mt. Sinai's proposal to RFP 737. In addition, JHS agrees to pay the County the amount of $40,000 during the first one-year term of this Agreement, in consideration of the County's additional costs in obtaining medical testing services from Mt. Sinai during the period of negotiation of this Agreement. These rates are guaranteed not to increase for the five-year contract term.

TITLE: Employees Testing & Medical Assessment Services

TERM: Five Years

CONTRACT AMOUNT: $4,500,000 for the initial five-year agreement to include an Option To Renew (OTR) for two years.

USING/MANAGING AGENCIES AND FUNDING SOURCES:

Department	Allocation	Funding Source	Project Manager
Internal Services	$ 4,500,000	Various (funded by hiring departments)	Michael Edwards
Total	**$ 4,500,000**		

ESTIMATED COMMENCEMENT DATE: December 17, 2011

BACKGROUND

Miami-Dade County conducts the following medical assessments and testing in accordance with established policies and protocols:

1. Pre-employment physical examinations for all applicants considered for employment;
2. High stress examinations for employees within designated classifications;
3. In-service fitness for duty assessments; and
4. Drug and alcohol testing for employees and applicants.

On June 7, 2011, the County Manager recommended award of contract RFP 737 to Mt. Sinai. The Board deferred the prior item to no time certain and instructed staff to evaluate the JHS' ability to fulfill the County's medical assessment and testing services requirements and to present a recommendation to the Board prior to December 17, 2011. The current contract with Mt. Sinai was to expire on June 17, 2011 but was extended by the Board for an additional six months under the same terms and conditions set forth in the existing contract.

The Human Resources Division of the Internal Services Department assembled an evaluation team with representatives from the following departments that have specialized services requirements: Miami-Dade Police, Miami-Dade Fire and Rescue, Miami-Dade Transit, Corrections and Rehabilitation, and Internal Services.

The evaluation committee, in collaboration with JHS, conducted a thorough review of the proposed health facilities and administrative procedures to determine if JHS could provide the desired services. The committee visited all five sites, confirmed that the facilities were able to deal with the expected volume of employees and applicants, verified that the equipment utilized to conduct tests was adequate, verified the credentials and certification of personnel, and conducted an evaluation of 20 critical factors that are requirements specified on the scope or services (Attachment 1).

The committee concluded that JHS was not only able to efficiently perform all necessary medical assessment and testing functions, but would also be capable of providing the following additional service enhancements:

- Facilities are located in areas that can accommodate Miami-Dade Transit requirements (Attachment 2). Pursuant to federal Department of Transportation regulations, employees must be tested within two hours after an accident;
- Easy access to the JHS Downtown Medical Center via public transportation;
- Ability to perform high stress physicals (phase I and II) within the same day, thereby reducing the amount of time employees are away from work;
- Perform fitness for duty evaluations and access to medical specialists in the same visit which would expedite evaluations.

The Collective Bargaining Agreement between Miami-Dade County and the Dade County Association of Firefighters (IAFF Local 1403) requires that physical examinations be conducted at facilities mutually agreeable to the County and IAFF Local 1403. The IAFF Local 1403 was advised of the committee's evaluation and concurs with the committee's recommendation.

Because the recommended award under this item is for the same services contemplated in RFP 737, the prior item has been placed on this agenda. This item supersedes the prior recommendation and rejects all proposals received in connection with the RFP.

Deputy Mayor

MEMORANDUM

(Revised)

TO: Honorable Chairman Joe A. Martinez and Members, Board of County Commissioners

DATE: November 15, 2011

FROM: R. A. Cuevas, Jr. County Attorney

SUBJECT: Agenda Item No. 8(F)(16)

Please note any items checked.

_____ **"3-Day Rule" for committees applicable if raised**

_____ **6 weeks required between first reading and public hearing**

_____ **4 weeks notification to municipal officials required prior to public hearing**

_____ **Decreases revenues or increases expenditures without balancing budget**

_____ **Budget required**

_____ **Statement of fiscal impact required**

_____ **Ordinance creating a new board requires detailed County Manager's report for public hearing**

✓ **No committee review**

_____ **Applicable legislation requires more than a majority vote (i.e., 2/3's ____, 3/5's ____, unanimous_____) to approve**

✓ **Current information regarding funding source, index code and available balance, and available capacity (if debt is contemplated) required**

Approved _____ Mayor
Veto _____
Override _____

Agenda Item No. 8(F)(16)
11-15-11

RESOLUTION NO. _____

RESOLUTION AUTHORIZING EXECUTION OF AN AGREEMENT IN THE AMOUNT OF $4,500,000 WITH THE PUBLIC HEALTH TRUST D.B.A. JACKSON HEALTH SYSTEM, TO PROVIDE EMPLOYEE TESTING AND MEDICAL ASSESSMENT SERVICES, AUTHORIZING THE COUNTY MAYOR OR COUNTY MAYOR'S DESIGNEE TO EXECUTE AN AGREEMENT FOR AND ON BEHALF OF MIAMI-DADE COUNTY AND TO EXERCISE ANY CANCELLATION AND RENEWAL PROVISIONS, AND TO EXERCISE ALL OTHER RIGHTS CONTAINED THEREIN

WHEREAS, this Board desires to accomplish the purposes outlined in the accompanying memorandum, a copy of which is incorporated herein by reference,

NOW, THEREFORE, BE IT RESOLVED BY THE BOARD OF COUNTY COMMISSIONERS OF MIAMI-DADE COUNTY, FLORIDA, that this Board approves pursuant to Section 2-9 and 2-10 of the Code of Miami-Dade County the execution of an agreement in the amount of $4,500,000 with The Public Health Trust d.b.a. Jackson Health System, an agency and instrumentality of the County, in substantially the form attached hereto and made a part hereof, and authorizes the County Mayor or County Mayor's designee to execute same for and on behalf of Miami-Dade County and to exercise any cancellation and renewal provisions and all other rights contained therein. The Board rejects all proposals received in connection with RFP 737, Employee Testing and Medical Assessment Services.

The foregoing resolution was offered by Commissioner , who moved its adoption. The motion was seconded by Commissioner and upon being put to a vote, the vote was as follows:

Joe A. Martinez, Chairman
Audrey M. Edmonson, Vice Chairwoman

Bruno A. Barreiro	Lynda Bell
Esteban L. Bovo, Jr.	Jose "Pepe" Diaz
Sally A. Heyman	Barbara J. Jordan
Jean Monestime	Dennis C. Moss
Rebeca Sosa	Sen. Javier D. Souto
Xavier L. Suarez	

The Chairperson thereupon declared the resolution duly passed and adopted this 15th day of November, 2011. This resolution shall become effective ten (10) days after the date of its adoption unless vetoed by the Mayor, and if vetoed, shall become effective only upon an override by this Board.

MIAMI-DADE COUNTY, FLORIDA
BY ITS BOARD OF
COUNTY COMMISSIONERS

HARVEY RUVIN, CLERK

By:_____
Deputy Clerk

Approved by County Attorney as
to form and legal sufficiency.

Hugo Benitez

ATTACHMENT 1

JMH Evaluation Summary

October 21, 2011

Miami Dade County JMH Committee Evaluation Summary
Committee Members:
Cristine Rogers, MDFR Chief
Derick Gordon, MDT Assistant Director
Edsel Abreu, HR Operations Manager
Eliel Flores, HR Employee Files Supervisor
Jay, Flynn, MDT HR Chief
Louvenia Lee, MDC&R Special Projects Administrator
Maritza Marti, HR Program Developer
Mike Edwards, HR Sr. Labor Management Specialist
Mike Viera, MDT Admin Officer 3
Sandra Gamble, MDT HR Manager
Temple Carpenter, MDPD Captain

Results:

Minimum Requirements:		Yes	No	Comments
2A	Are physicians licensed by the State of Florida, Department of Health, Division of Medical Quality Assurance?	X		
2B	Are the facilities licensed by the State of Florida, Agency for Health Care Administration?	X		

Services Provided:

3.1	Able to perform:			
	pre-employment physicals	X		
	high stress	X		
	fitness for duty	X		
	drug & alcohol	X		
3.2	Is the assessment service provider a Board Certified Internal Medicine or Family Practice State of Florida license (male and female) physician?	X		
3.3	Is the facility able to conduct all appointments for pre-employment M-Fr 8:00 am to 5:00 pm?	X		

3.4	Conduct high stress physical examinations in two visits			
	Phase I: M-Fr 7:00 am to 10:00 am	X		
	Phase II: no later than three days after phase I (Between 0-3 days)	X		
3.5	Can JMH perform all appointments for fitness for duty within two days of appointment confirmation?	X		
3.6	Is at least one facility open 24/7	X		
3.7	Is the Medical Review Officer certified?	X		
3.8	Is the interpretation of X-Ray and EKG conducted by a Board Certified Specialist?	X		
3.9	Are re-examinations and/or re-testing of employees/applicants conducted at no charge?	X		
3.10	Are independent medical reviews available?	X		
3.11	Is the collection of drug/alcohol screening testing in compliance with established procedures and protocols?	X		
	Is there at least one breath alcohol technician at the facility?	X		
3.12	Is the area for specimen collection secured?	X		
3.13	Are the urine collecting kits comprise of a collection container, plastic specimen bottles, leak resistant plastic bag, absorbent material, and shipping container?	X		
3.14	Is on-site specimen collection available 24/7?	X		
	Is the mobile specimen collection available no later than three business days after a request?	X		

3.15	Are medical monitoring and safety issues handled in accordance with established protocols?	X		
3.16	Does the facility provide a private area to allow County employees to perform fingerprints and administrative functions as necessary?	X		
3.17	Does the facility provide individual, secure storage lockers at each location for use of all examinees?	X		
3.18	Is JMH willing to assist with ADA, FMLA, and related actions to redesign and update protocols?	X		

Comments:

Attachment 2

FACILITY, LOCATION, OPERATION AND SERVICES PROVIDED

Facility	Location	Days and Hours of Operation	Services Provided
Jackson North Medical Center	160 N.W. 170th Street North Miami Beach, FL 33169	Monday to Friday 7:00 a.m. to 5:00 p.m.	• Pre-employment and annual physical examinations • High stress physical examinations • Fitness for duty examinations • Drug/alcohol testing assessments
Jackson South Community Hospital	9333 S.W. 152nd Street Miami, FL 33157	Monday to Friday 7:00 a.m. to 5:00 p.m.	• Pre-employment and annual physical examinations • High stress physical examinations • Fitness for duty examinations • Drug/alcohol testing assessments
Biscayne Medical Plaza	3801 Biscayne Blvd. Miami, FL 33137	Monday to Friday 7:00 a.m. to 5:00 p.m.	• Pre-employment and annual physical examinations • High stress physical examinations • Fitness for duty examinations • Drug/alcohol testing assessments
Downtown Medical Center	111 N.W. 1st Street SPCC Ground Floor Miami, FL 33128	Monday to Friday 7:00 a.m. to 5:00 p.m.	• Pre-employment and annual physical examinations • Fitness for duty examinations • Drug/alcohol testing assessments
Jackson Memorial Hospital (Emergency Room)	1611 N.W. 12th Avenue Miami, FL 33136	24 hours/7 days a week	• Pre-employment and annual physical examinations • High stress physical examinations • Fitness for duty examinations • Drug/alcohol testing assessments

D

Employee Testing & Medical Assessment Services

Intergovernmental Agreement

THIS AGREEMENT made and entered into as of this 4th day of November by and between The Public Health Trust d.b.a Jackson Health System an agency of Miami Dade County/Public Health Trust and existing under the laws of the State of Florida, having its principal office at 1611 N.W. 12th Avenue , Miami, Florida 33136 (hereinafter referred to as the "Agency"), and Miami-Dade County, a political subdivision of the State of Florida, having its principal office at 111 N.W. 1st Street, Miami, Florida 33128 (hereinafter referred to as the "County"),

WITNESSETH:

WHEREAS, the Agency has offered to provide employee testing and medical assessment services, on a non-exclusive basis, that shall conform to the Scope of Services (Appendix A); Miami-Dade County's Request for all associated addenda and attachments, incorporated herein by reference; and the requirements of this Agreement; and,

WHEREAS, the Agency has submitted a written proposal dated August 22, 2011, hereinafter referred to as the "Agency's Proposal" which is incorporated herein by reference; and,

WHEREAS, the County desires to procure from the Agency such employee testing and medical assessment services for the County, in accordance with the terms and conditions of this Agreement;

NOW, THEREFORE, in consideration of the mutual covenants and agreements herein contained, the parties hereto agree as follows:

ARTICLE 1. DEFINITIONS

The following words and expressions used in this Agreement shall be construed as follows, except when it is clear from the context that another meaning is intended:

a) The words "Contract" or "Contract Documents" or "Agreement" to mean collectively these terms and conditions, the Scope of Services (Appendix A), Price Schedule (Appendix B), and Business Associate Agreement (Appendix C), Miami-Dade County's Employee Medical Assessment and Testing Procedure Protocols A-F3 (Appendix D) and all associated addenda and attachments, the Agency's Proposal, and all other attachments hereto and all amendments issued hereto.

b) The words "Contract Date" to mean the date on which this Agreement is effective.

c) The words "Contract Manager" to mean Miami-Dade County's Director, Human Resources Division of Internal Services Department, or the duly authorized representative designated to manage the Contract.

d) The word "Agency" to mean The Public Health Trust d.b.a Jackson Health System and its permitted successors and assigns.

e) The word "Days" to mean Calendar Days.

f) The word "Deliverables" to mean all documentation and any items of any nature submitted by the Agency to the County's Project Manager for review and approval pursuant to the terms of this Agreement.

g) The words "directed", "required", "permitted", "ordered", "designated", "selected", "prescribed" or words of like import to mean respectively, the direction, requirement, permission, order, designation, selection or prescription of the County's Project Manager; and similarly the words "approved", acceptable", "satisfactory", "equal", "necessary", or words of like import to mean respectively, approved by, or acceptable or satisfactory to, equal or necessary in the opinion of the County's Project Manager.

h) The words "Change Order" or "Extra Work" or "Additional Work" resulting in additions or deletions or modifications to the amount, type or value of the Work and Services as required in this Contract, as directed and/or approved by the County.

i) The words "Project Manager" to mean the Mayor or the duly authorized representative designated to manage the Project.

j) The words "Scope of Services" to mean the document appended hereto as Appendix A, which details the work to be performed by the Agency.

k) The word "subAgency" or "subconsultant" to mean any person, entity, firm or corporation, other than the employees of the Agency, who furnishes labor and/or materials, in connection with the Work, whether directly or indirectly, on behalf and/or under the direction of the Agency and whether or not in privity of Contract with the Agency.

l) The words "Work", "Services" "Program", or "Project" to mean all matters and things required to be done by the Agency in accordance with the provisions of this Contract.

ARTICLE 2. ORDER OF PRECEDENCE

If there is a conflict between or among the provisions of this Agreement, the order of precedence is as follows: 1) these terms and conditions, 2) Appendices to these terms and conditions (the Scope of Services, Price Schedule, Business Associate Agreement and Miami-Dade County's Employee Medical Assessment and Testing Procedure Protocols A-F3), 3) the Miami-Dade County's associated addenda and attachments thereof, and 4) the Agency's Proposal.

ARTICLE 3. RULES OF INTERPRETATION

a) References to a specified Article, section or schedule shall be construed as reference to that specified Article, or section of, or schedule to this Agreement unless otherwise indicated.

b) Reference to any agreement or other instrument shall be deemed to include such agreement or other instrument as such agreement or other instrument may, from time to time, be modified, amended, supplemented, or restated in accordance with its terms.

c) The terms "hereof", "herein", "hereinafter", "hereby", "herewith", "hereto", and "hereunder" shall be deemed to refer to this Agreement.

d) The titles, headings, captions and arrangements used in these Terms and Conditions are for convenience only and shall not be deemed to limit, amplify or modify the terms of this Contract, nor affect the meaning thereof.

ARTICLE 4. NATURE OF THE AGREEMENT

a) This Agreement incorporates and includes all prior negotiations, correspondence, conversations, agreements, and understandings applicable to the matters contained in this Agreement. The parties agree that there are no commitments, agreements, or understandings concerning the subject matter of this Agreement that are not contained in this Agreement, and that this Agreement contains the entire agreement between the parties as to all matters contained herein. Accordingly, it is agreed that no deviation from the terms hereof shall be predicated upon any prior representations or agreements, whether oral or written. It is further agreed that any oral representations or modifications concerning this Agreement shall be of no force or effect, and that this Agreement may be modified, altered or amended only by a written amendment duly executed by both parties hereto or their authorized representatives.

b) The Agency shall provide the services set forth in the Scope of Services, and render full and prompt cooperation with the County in all aspects of the Services performed hereunder.

c) The Agency acknowledges that this Agreement requires the performance of all things necessary for or incidental to the effective and complete performance of all Work and Services under this Contract. All things not expressly mentioned in this Agreement but necessary to carrying out its intent are required by this Agreement, and the Agency shall perform the same as though they were specifically mentioned, described and delineated.

d) The Agency shall furnish all labor, materials, tools, supplies, and other items required to

perform the Work and Services that are necessary for the completion of this Contract. All Work and Services shall be accomplished at the direction of and to the satisfaction of the County's Project Manager.

e) The Agency acknowledges that the County shall be responsible for making all policy decisions regarding the Scope of Services. The Agency agrees to provide input on policy issues in the form of recommendations. The Agency agrees to implement any and all changes in providing Services hereunder as a result of a policy change implemented by the County. The Agency agrees to act in an expeditious and fiscally sound manner in providing the County with input regarding the time and cost to implement said changes and in executing the activities required to implement said changes.

ARTICLE 5. CONTRACT TERM

The Contract shall become effective on the date set forth on the first page and shall continue through the last day of the 60th month. The County, at its sole discretion, reserves the right to exercise the option to renew this Contract for a period for two (2) additional years. The County reserves the right to exercise its option to extend this Contract for up to one hundred-eighty (180) calendar days beyond the current Contract period and will notify the Agency in writing of the extension. This Contract may be extended beyond the initial one hundred-eighty (180) calendar day extension period by mutual agreement between the County and the Agency, upon approval by the Board of County Commissioners.

ARTICLE 6. NOTICE REQUIREMENTS

All notices required or permitted under this Agreement shall be in writing and shall be deemed sufficiently served if delivered by Registered or Certified Mail, with return receipt requested; or delivered personally; or delivered via fax or e-mail (if provided below) and followed with delivery of hard copy; and in any case addressed as follows:

(1) to the County

a) to the Project Manager:

Miami-Dade County
Human Resources Division, Internal Services Department
111 N. W. 1 Street, Suite 2140
Miami, FL 33128
Attention: Michael Edwards
Phone: (305) 375-2479
Fax: (305) 375-4138
E-mail: MXX@miamidade.gov

and,

b) to the Agreement Manager:

Miami-Dade County
Human Resources Division, Internal Services Department
111 N.W. 1st Street, Suite 2110

Miami, FL 33128-1974
Attention: Edsel Abreu
Phone: (305) 375-4056
Fax: (305) 375-2459
E-mail: Eabreu@miamidade.gov

(2) To the Agency

Jackson Health System
1611 N.W. 12th Avenue
Miami, Florida 33136-1096
Attention: Barbara Ronda, Vice President
Phone: (305) 305-6086
Fax: (305) 355-2372
E-mail: BRonda@jhsmiami.org

Either party may at any time designate a different address and/or contact person by giving notice as provided above to the other party. Such notices shall be deemed given upon receipt by the addressee.

ARTICLE 7. PAYMENT FOR SERVICES/AMOUNT OBLIGATED

The Agency warrants that it has reviewed the County's requirements and has asked such questions and conducted such other inquiries as the Agency deemed necessary in order to determine the price the Agency will charge to provide the Work and Services to be performed under this Contract. The compensation for all Work and Services performed under this Contract, including all costs associated with such Work and Services, shall be as stipulated in Appendix B – Price Schedule. The County shall have no obligation to pay the Agency any additional sum in excess of this amount, except for a change and/or modification to the Contract, which is approved and executed in writing by the County and the Agency.

All Services undertaken by the Agency before County's approval of this Contract shall be at the Agency's risk and expense.

ARTICLE 8. PRICING

Prices shall remain firm and fixed for the initial term of the Contract. The prices for any option or extension periods will be in accordance with Appendix B – Price Schedule. However, the Agency may offer incentive discounts to the County at any time during the Contract term, including any renewal or extension thereof.

The Jackson Health System agrees to pay the County the amount of $40,000 during the first one year term of this agreement, in consideration of the County's additional costs in obtaining medical testing services during the period of negotiation of this agreement. The parties shall determine by mutual agreement the method to credit or pay the County this amount during the one year period.

ARTICLE 9. METHOD AND TIMES OF PAYMENT

The Agency agrees that under the provisions of this Agreement, as reimbursement for those actual, reasonable and necessary costs incurred by the Agency, which are directly attributable or properly allocable to the Services, the Agency will bill the County once per month, upon invoices certified by the Agency pursuant to Appendix B – Price Schedule. All invoices shall be taken from the books of account kept by the Agency, shall be supported by
copies of payroll distributions, receipt bills or other documents reasonably required by the County, shall show the County's contract number, and shall have a unique invoice number assigned by the Agency. Agency shall submit invoice electronically in Excel format to the County and include the following itemized information:

- List of each examinee by name and social security number;
- Description of examination and testing services rendered;
- Date of service(s) and examination type code as indicated in Appointment Schedule Form;

Payment will not be processed for services rendered until the complete Physical Examination and Drug/Alcohol Results Package is submitted to the County. The Agency shall address all invoice discrepancies as identified by the County and submit requested documentation for consideration and final approval.

It is the policy of Miami-Dade County that payment for all purchases by County agencies and the Public Health Trust shall be made in a timely manner and that interest payments be made on late payments. In accordance with Florida Statutes, Section 218.74 and Section 2-8.1.4 of the Miami-Dade County Code, the time at which payment shall be due from the County or the Public Health Trust shall be forty-five (45) days from receipt of a proper invoice. The time at which payment shall be due to small businesses shall be thirty (30) days from receipt of a proper invoice. All payments due from the County or the Public Health Trust, and not made within the time specified by this section shall bear interest from thirty (30) days after the due date at the rate of one percent (1%) per month on the unpaid balance. Further, proceedings to resolve disputes for payment of obligations shall be concluded by final written decision of the County Manager, or his or her designee(s), not later that sixty (60) days after the date on which the proper invoice was received by the County or the Public Health Trust.

Invoices and associated back-up documentation shall be submitted in duplicate by the Agency to the County as follows:

Miami-Dade County
Human Resources Division, Internal Services Department
111 N. W. 1 Street, Suite 2140
Miami, FL 33128
Attention: Michael Edwards

The County may at any time designate a different address and/or contact person by giving written notice to the other party.

ARTICLE 10. INDEMNIFICATION AND INSURANCE

Jackson Health System (JHS) shall indemnify and hold harmless the County and its officers, employees, agents and instrumentalities from any and all liability, losses or damages, including attorney's fees and costs of defense, which County may incur as a result of claims, demands,

suits, causes of actions or proceedings of any kind or nature arising out of, relating to or resulting from the performance of the Agreement by JHS. Provided, however, this indemnification shall only be to the extent and within the limitations of Section 768.28 Florida Statutes, subject to the provisions of the Statute whereby JHS shall not be held liable to pay a personal injury or property damage claim or judgment by any one person which exceeds the sum of $200,000, or any claim or judgment or portions thereof, which when totaled with all other claims or judgments paid by the Provider arising out of the same incident or occurrence, exceed the sum of $300,000 from any and all personal injury or property damage claims, liabilities, losses or causes of action which may arise as a result of the negligence of JHS.

ARTICLE 11. MANNER OF PERFORMANCE

a) The Agency shall provide the Services described herein in a competent and professional manner satisfactory to the County in accordance with the terms and conditions of this Agreement. The County shall be entitled to a satisfactory performance of all Services described herein and to full and prompt cooperation by the Agency in all aspects of the Services. At the request of the County the Agency shall promptly remove from the project any Agency's employee, subAgency, or any other person performing Services hereunder. The Agency agrees that such removal of any of its employees does not require the termination or demotion of any employee by the Agency.

b) The Agency agrees to defend, hold harmless and indemnify the County and shall be liable and responsible for any and all claims, suits, actions, damages and costs (including attorney's fees and court costs) made against the County, occurring on account of, arising from or in connection with the removal and replacement of any Agency's personnel performing services hereunder at the behest of the County. Removal and replacement of any Agency's personnel as used in this Article shall not require the termination and or demotion of such Agency's personnel.

c) The Agency agrees that at all times it will employ, maintain and assign to the performance of the Services a sufficient number of competent and qualified professionals and other personnel to meet the requirements to which reference is hereinafter made. The Agency agrees to adjust its personnel staffing levels or to replace any its personnel if so directed upon reasonable request from the County, should the County make a determination, in its sole discretion, that said personnel staffing is inappropriate or that any individual is not performing in a manner consistent with the requirements for such a position.

d) The Agency warrants and represents that its personnel have the proper skill, training, background, knowledge, experience, rights, authorizations, integrity, character and licenses as necessary to perform the Services described herein, in a competent and professional manner.

e) The Agency shall at all times cooperate with the County and coordinate its respective work efforts to most effectively and efficiently maintain the progress in performing the Services.

f) The Agency shall comply with all provisions of all federal, state and local laws, statutes, ordinances, and regulations that are applicable to the performance of this Agreement.

ARTICLE 12. EMPLOYEES ARE THE RESPONSIBILITY OF THE AGENCY

All employees of the Agency shall be considered to be, at all times, employees of the Agency under its sole direction and not employees or agents of the County. The Agency shall supply competent employees. Miami-Dade County may require the Agency to remove an employee it deems careless, incompetent, insubordinate or otherwise objectionable and whose continued employment on County property is not in the best interest of the County. Each employee shall have and wear proper identification.

ARTICLE 13. INDEPENDENT AGENCY RELATIONSHIP

The Agency is, and shall be, in the performance of all work services and activities under this Agreement, an independent Agency, and not an employee, agent or servant of the County. All persons engaged in any of the work or services performed pursuant to this Agreement shall at all times, and in all places, be subject to the Agency's sole direction, supervision and control. The Agency shall exercise control over the means and manner in which it and its employees perform the work, and in all respects the Agency's relationship and the relationship of its employees to the County shall be that of an independent Agency and not as employees and agents of the County.

The Agency does not have the power or authority to bind the County in any promise, agreement or representation other than specifically provided for in this Agreement.

ARTICLE 14. AUTHORITY OF THE COUNTY'S PROJECT MANAGER

a) The Agency hereby acknowledges that the County's Project Manager will determine in the first instance all questions of any nature whatsoever arising out of, under, or in connection with, or in any way related to or on account of, this Agreement including without limitations: questions as to the value, acceptability and fitness of the Services; questions as to either party's fulfillment of its obligations under the Contract; negligence, fraud or misrepresentation before or subsequent to acceptance of the Agency's Proposal; questions as to the interpretation of the Scope of Services; and claims for damages, compensation and losses.

b) The Agency shall be bound by all determinations or orders and shall promptly obey and follow every order of the Project Manager, including the withdrawal or modification of any previous order and regardless of whether the Agency agrees with the Project Manager's determination or order. Where orders are given orally, they will be issued in writing by the Project Manager as soon thereafter as is practicable.

c) The Agency must, in the final instance, seek to resolve every difference concerning the Agreement with the Project Manager. In the event that the Agency and the Project Manager are unable to resolve their difference, the Agency may initiate a dispute in accordance with the procedures set forth in this Article. Exhaustion of these procedures shall be a condition precedent to any lawsuit permitted hereunder.

d) In the event of such dispute, the parties to this Agreement authorize the County Manager or designee, who may not be the Project Manager or anyone associated with this Project, acting personally, to decide all questions arising out of, under, or in connection with, or in any way related to or on account of the Agreement (including but not limited to claims in the nature of breach of contract, fraud or misrepresentation

arising either before or subsequent to execution hereof) and the decision of each with respect to matters within the County Manager's purview as set forth above shall be conclusive, final and binding on parties. Any such dispute shall be brought, if at all, before the County Manager within 10 days of the occurrence, event or act out of which the dispute arises.

e) The County Manager may base this decision on such assistance as may be desirable, including advice of experts, but in any event shall base the decision on an independent and objective determination of whether Agency's performance or any Deliverable meets the requirements of this Agreement and any specifications with respect thereto set forth herein. The effect of any decision shall not be impaired or waived by any negotiations or settlements or offers made in connection with the dispute, whether or not the County Manager participated therein, or by any prior decision of others, which prior decision shall be deemed subject to review, or by any termination or cancellation of the Agreement. All such disputes shall be submitted in writing by the Agency to the County Manager for a decision, together with all evidence and other pertinent information in regard to such questions, in order that a fair and impartial decision may be made. Whenever the County Manager is entitled to exercise discretion or judgement or to make a determination or form an opinion pursuant to the provisions of this Article, such action shall be fair and impartial when exercised or taken. The County Manager, as appropriate, shall render a decision in writing and deliver a copy of the same to the Agency. Except as such remedies may be limited or waived elsewhere in the Agreement, Agency reserves the right to pursue any remedies available under law after exhausting the provisions of this Article.

ARTICLE 15. MUTUAL OBLIGATIONS

a) This Agreement, including attachments and appendixes to the Agreement, shall constitute the entire Agreement between the parties with respect hereto and supersedes all previous communications and representations or agreements, whether written or oral, with respect to the subject matter hereto unless acknowledged in writing by the duly authorized representatives of both parties.

b) Nothing in this Agreement shall be construed for the benefit, intended or otherwise, of any third party that is not a parent or subsidiary of a party or otherwise related (by virtue of ownership control or statutory control) to a party.

c) In those situations where this Agreement imposes an indemnity obligation on the Agency, the County may, at its expense, elect to participate in the defense if the County should so choose. Furthermore, the County may at its own expense defend or settle any such claims if the Agency fails to diligently defend such claims, and thereafter seek indemnity for costs from the Agency.

ARTICLE 16. QUALITY ASSURANCE/QUALITY ASSURANCE RECORD KEEPING

The Agency shall maintain, and shall require that its subAgencys and suppliers maintain, complete and accurate records to substantiate compliance with the requirements set forth in the Scope of Services. The Agency and its subAgencys and suppliers, shall retain such records, and all other documents relevant to the Services furnished under this Agreement for a period of three (3) years from the expiration date of this Agreement and any extension thereof.

ARTICLE 17. AUDITS

The County, or its duly authorized representatives or governmental agencies shall, until the expiration of three (3) years after the expiration of this Agreement and any extension thereof, have access to and the right to examine and reproduce any of the Agency's books, documents, papers and records and of its subAgencys and suppliers which apply to all matters of the County. Such records shall subsequently conform to Generally Accepted Accounting Principles requirements, as applicable, and shall only address those transactions related to this Agreement.

Pursuant to County Ordinance No. 03-2, the Agency will grant access to the Commission Auditor to all financial and performance related records, property, and equipment purchased in whole or in part with government funds. The Agency agrees to maintain an accounting system that provides accounting records that are supported with adequate documentation, and adequate procedures for determining the allowability and allocability of costs.

ARTICLE 18. SUBSTITUTION OF PERSONNEL

In the event the Agency wishes to substitute personnel for the key personnel identified by the Agency's Proposal, the Agency must notify the County in writing and request written approval for the substitution at least ten (10) business days prior to effecting such substitution.

ARTICLE 19. CONSENT OF THE COUNTY REQUIRED FOR ASSIGNMENT

The Agency shall not assign, transfer, convey or otherwise dispose of this Agreement, including its rights, title or interest in or to the same or any part thereof without the prior written consent of the County.

ARTICLE 20. SUBCONTRACTUAL RELATIONS

a) If the Agency will cause any part of this Agreement to be performed by a SubAgency, the provisions of this Contract will apply to such SubAgency and its officers, agents and employees in all respects as if it and they were employees of the Agency; and the Agency will not be in any manner thereby discharged from its obligations and liabilities hereunder, but will be liable hereunder for all acts and negligence of the SubAgency, its officers, agents, and employees, as if they were employees of the Agency. The services performed by the SubAgency will be subject to the provisions hereof as if performed directly by the Agency.

b) The Agency, before making any subcontract for any portion of the services, will state in writing to the County the name of the proposed SubAgency, the portion of the Services which the SubAgency is to do, the place of business of such SubAgency, and such other information as the County may require. The County will have the right to require the Agency not to award any subcontract to a person, firm or corporation disapproved by the County.

c) Before entering into any subcontract hereunder, the Agency will inform the SubAgency fully and completely of all provisions and requirements of this Agreement relating either directly or indirectly to the Services to be performed. Such Services performed by such SubAgency will strictly comply with the requirements of this Contract.

d) In order to qualify as a SubAgency satisfactory to the County, in addition to the other requirements herein provided, the SubAgency must be prepared to prove to the satisfaction of the County that it has the necessary facilities, skill and experience, and ample financial resources to perform the Services in a satisfactory manner. To be considered skilled and experienced, the SubAgency must show to the satisfaction of the County that it has satisfactorily performed services of the same general type which is required to be performed under this Agreement.

e) The County shall have the right to withdraw its consent to a subcontract if it appears to the County that the subcontract will delay, prevent, or otherwise impair the performance of the Agency's obligations under this Agreement. All SubAgencys are required to protect the confidentiality of the County's and County's proprietary and confidential information. Agency shall furnish to the County copies of all subcontracts between Agency and SubAgencys and suppliers hereunder. Within each such subcontract, there shall be a clause for the benefit of the County permitting the County to request completion of performance by the SubAgency of its obligations under the subcontract, in the event the County finds the Agency in breach of its obligations, the option to pay the SubAgency directly for the performance by such subAgency. Notwithstanding, the foregoing shall neither convey nor imply any obligation or liability on the part of the County to any subAgency hereunder as more fully described herein.

ARTICLE 21. ASSUMPTION, PARAMETERS, PROJECTIONS, ESTIMATES AND EXPLANATIONS

The Agency understands and agrees that any assumptions, parameters, projections, estimates and explanations presented by the County were provided to the Agency for evaluation purposes only. However, since these assumptions, parameters, projections, estimates and explanations represent predictions of future events the County makes no representations or guarantees; and the County shall not be responsible for the accuracy of the assumptions presented; and the County shall not be responsible for conclusions to be drawn therefrom; and any assumptions, parameters, projections, estimates and explanations shall not form the basis of any claim by the Agency. The Agency accepts all risk associated with using this information.

ARTICLE 22. SEVERABILITY

If this Agreement contains any provision found to be unlawful, the same shall be deemed to be of no effect and shall be deemed stricken from this Agreement without affecting the binding force of this Agreement as it shall remain after omitting such provision.

ARTICLE 23. TERMINATION AND SUSPENSION OF WORK

a) The County may terminate this Agreement if an individual or corporation or other entity attempts to meet its contractual obligation with the County through fraud, misrepresentation or material misstatement.

b) The County may, as a further sanction, terminate or cancel any other contract(s) that such individual or corporation or other entity has with the County and that such individual, corporation or other entity shall be responsible for all direct and indirect costs associated with such termination or cancellation, including attorney's fees.

c) The foregoing notwithstanding, any individual, corporation or other entity which attempts to meet its contractual obligations with the County through fraud, misrepresentation or material misstatement may be debarred from County contracting for up to five (5) years in accordance with the County debarment procedures. The Agency may be subject to debarment for failure to perform and all other reasons set forth in Section 10-38 of the County Code.

In addition to cancellation or termination as otherwise provided in this Agreement, the County may at any time, in its sole discretion, with or without cause, terminate this Agreement by written notice to the Agency and in such event:

d) The Agency shall, upon receipt of such notice, unless otherwise directed by the County:

i. stop work on the date specified in the notice ("the Effective Termination Date");

ii. take such action as may be necessary for the protection and preservation of the County's materials and property;

iii. cancel orders;

iv. assign to the County and deliver to any location designated by the County any noncancelable orders for Deliverables that are not capable of use except in the performance of this Agreement and has been specifically developed for the sole purpose of this Agreement and not incorporated in the Services:

v. take no action which will increase the amounts payable by the County under this Agreement; and

e) In the event that the County exercises its right to terminate this Agreement pursuant to this Article the Agency will be compensated as stated in the payment Articles, herein, for the:

i. portion of the Services completed in accordance with the Agreement up to the Effective Termination Date; and

ii. noncancelable Deliverables that are not capable of use except in the performance of this Agreement and has been specifically developed for the sole purpose of this Agreement but not incorporated in the Services.

f) All compensation pursuant to this Article are subject to audit.

ARTICLE 24. EVENT OF DEFAULT

a) An Event of Default shall mean a breach of this Agreement by the Agency. Without limiting the generality of the foregoing and in addition to those instances referred to herein as a breach, an Event of Default, shall include the following:

i. the Agency has not delivered Deliverables on a timely basis.

ii. the Agency has refused or failed, except in case for which an extension of time is provided, to supply enough properly skilled Staff Personnel;

iii. the Agency has failed to make prompt payment to subAgencys or suppliers for any Services;

iv. the Agency has become insolvent (other than as interdicted by the bankruptcy laws), or has assigned the proceeds received for the benefit of the Agency's creditors, or the Agency has taken advantage of any insolvency statute or debtor/creditor law or if the Agency's affairs have been put in the hands of a receiver;

v. the Agency has failed to obtain the approval of the County where required by this Agreement;

vi. the Agency has failed to provide "adequate assurances" as required under subsection "b" below;

vii. the Agency has failed in the representation of any warranties stated herein.

b) When, in the opinion of the County, reasonable grounds for uncertainty exist with respect to the Agency's ability to perform the Services or any portion thereof, the County may request that the Agency, within the timeframe set forth in the County's request, provide adequate assurances to the County, in writing, of the Agency's ability to perform in accordance with terms of this Agreement. Until the County receives such assurances the County may request an adjustment to the compensation received by the Agency for portions of the Services which the Agency has not performed. In the event that the Agency fails to provide to the County the requested assurances within the prescribed time frame, the County may:

i. treat such failure as a repudiation of this Agreement;

ii. resort to any remedy for breach provided herein or at law, including but not limited to, taking over the performance of the Services or any part thereof either by itself or through others.

c) In the event the County shall terminate this Agreement for default, the County or its designated representatives, may immediately take possession of all applicable equipment, materials, products, documentation, reports and data.

ARTICLE 25. NOTICE OF DEFAULT - OPPORTUNITY TO CURE

If an Event of Default occurs, in the determination of the County, the County may so notify the Agency ("Default Notice"), specifying the basis for such default, and advising the Agency that such default must be cured immediately or this Agreement with the County may be terminated. Notwithstanding, the County may, in its sole discretion, allow the Agency to rectify the default to the County's reasonable satisfaction within a thirty (30) day period. The County may grant an additional period of such duration as the County shall deem appropriate without waiver of any of the County's rights hereunder, so long as the Agency has commenced curing such default and is effectuating a cure with diligence and continuity during such thirty (30) day period or any other period which the County prescribes. The default notice shall specify the date the Agency shall discontinue the Services upon the Termination Date.

ARTICLE 26. REMEDIES IN THE EVENT OF DEFAULT

If an Event of Default occurs, the Agency shall be liable for all damages resulting from the default, including but not limited to:

a) lost revenues;

b) the difference between the cost associated with procuring Services hereunder and the amount actually expended by the County for reprocurement of Services, including procurement and administrative costs; and,

c) such other direct damages.

The Agency shall also remain liable for any liabilities and claims related to the Agency's default. The County may also bring any suit or proceeding for specific performance or for an injunction.

ARTICLE 27. PATENT AND COPYRIGHT INDEMNIFICATION

a) The Agency warrants that all Deliverables furnished hereunder, including but not limited to: equipment programs, documentation, software, analyses, applications, methods, ways, processes, and the like, do not infringe upon or violate any patent, copyrights, service marks, trade secret, or any other third party proprietary rights.

b) The Agency shall be liable and responsible for any and all claims made against the County for infringement of patents, copyrights, service marks, trade secrets or any other third party proprietary rights, by the use or supplying of any programs, documentation, software, analyses, applications, methods, ways, processes, and the like, in the course of performance or completion of, or in any way connected with, the Work, or the County's continued use of the Deliverables furnished hereunder. Accordingly, the Agency at its own expense, including the payment of attorney's fees, shall indemnify, and hold harmless the County and defend any action brought against the County with respect to any claim, demand, cause of action, debt, or liability.

c) In the event any Deliverable or anything provided to the County hereunder, or portion thereof is held to constitute an infringement and its use is or may be enjoined, the Agency shall have the obligation to, at the County's option to (i) modify, or require that the applicable subAgency or supplier modify, the alleged infringing item(s) at its own expense, without impairing in any respect the functionality or performance of the item(s), or (ii) procure for the County, at the Agency's expense, the rights provided under this Agreement to use the item(s).

d) The Agency shall be solely responsible for determining and informing the County whether a prospective supplier or subAgency is a party to any litigation involving patent or copyright infringement, service mark, trademark, violation, or proprietary rights claims or is subject to any injunction which may prohibit it from providing any Deliverable hereunder. The Agency shall enter into agreements with all suppliers and subAgencys at the Agency's own risk. The County may reject any Deliverable that it believes to be the subject of any such litigation or injunction, or if, in the County's judgment, use thereof would delay the Work or be unlawful.

e) The Agency shall not infringe any copyright, trademark, service mark, trade secrets, patent rights, or other intellectual property rights in the performance of the Work.

ARTICLE 28. CONFIDENTIALITY

a) All Developed Works and other materials, data, transactions of all forms, financial information, documentation, inventions, designs and methods obtained from the County in connection with the Services performed under this Agreement, made or developed by the Agency or its subAgencys in the course of the performance of such Services, or the results of such Services, or which the County holds the proprietary rights, constitute Confidential Information and may not, without the prior written consent of the County, be used by the Agency or its employees, agents, subAgencys or suppliers for any purpose other than for the benefit of the County, unless required by law. In addition to the foregoing, all County employee information and County financial information shall be considered confidential information and shall be subject to all the requirements stated herein. Neither the Agency nor its employees, agents, subAgencys or suppliers may sell, transfer, publish, disclose, display, license or otherwise make available to others any part of such Confidential Information without the prior written consent of the County. Additionally, the Agency expressly agrees to be bound by and to defend, indemnify and hold harmless the County, and their officers and employees from the breach of any federal, state or local law in regard to the privacy of individuals.

b) The Agency shall advise each of its employees, agents, subAgencys and suppliers who may be exposed to such Confidential Information of their obligation to keep such information confidential and shall promptly advise the County in writing if it learns of any unauthorized use or disclosure of the Confidential Information by any of its employees or agents, or subAgency's or supplier's employees, present or former. In addition, the Agency agrees to cooperate fully and provide any assistance necessary to ensure the confidentiality of the Confidential Information.

c) It is understood and agreed that in the event of a breach of this Article damages may not be an adequate remedy and the County shall be entitled to injunctive relief to restrain any such breach or threatened breach. Unless otherwise requested by the County, upon the completion of the Services performed hereunder, the Agency shall immediately turn over to the County all such Confidential Information existing in tangible form, and no copies thereof shall be retained by the Agency or its employees, agents, subAgencys or suppliers without the prior written consent of the County. A certificate evidencing compliance with this provision and signed by an officer of the Agency shall accompany such materials.

ARTICLE 29. PROPRIETARY INFORMATION

As a political subdivision of the State of Florida, Miami-Dade County is subject to the stipulations of Florida's Public Records Law.

The Agency acknowledges that all computer software in the County's possession may constitute or contain information or materials which the County has agreed to protect as proprietary information from disclosure or unauthorized use and may also constitute or contain information or materials which the County has developed at its own expense, the disclosure of which could harm the County's proprietary interest therein.

During the term of the contract, the Agency will not use directly or indirectly for itself or for others, or publish or disclose to any third party, or remove from the County's property, any computer programs, data compilations, or other software which the County has developed, has used or is using, is holding for use, or which are otherwise in the possession of the County (hereinafter "Computer Software"). All third-party license agreements must also be honored by the Agencys and their employees, except as authorized by the County and, if the Computer Software has been leased or purchased by the County, all hired party license agreements must also be honored by the Agencys' employees with the approval of the lessor or Agencys thereof. This includes mainframe, minis, telecommunications, personal computers and any and all information technology software.

The Agency will report to the County any information discovered or which is disclosed to the Agency which may relate to the improper use, publication, disclosure or removal from the County's property of any information technology software and hardware and will take such steps as are within the Agency's authority to prevent improper use, disclosure or removal.

ARTICLE 30. PROPRIETARY RIGHTS

a) The Agency hereby acknowledges and agrees that the County retains all rights, title and interests in and to all materials, data, documentation and copies thereof furnished by the County to the Agency hereunder or furnished by the Agency to the County and/or created by the Agency for delivery to the County, even if unfinished or in process, as a result of the Services the Agency performs in connection with this Agreement, including all copyright and other proprietary rights therein, which the Agency as well as its employees, agents, subAgencys and suppliers may use only in connection of the performance of Services under this Agreement. The Agency shall not, without the prior written consent of the County, use such documentation on any other project in which the Agency or its employees, agents, subAgencys or suppliers are or may become engaged. Submission or distribution by the Agency to meet official regulatory requirements or for other purposes in connection with the performance of Services under this Agreement shall not be construed as publication in derogation of the County's copyrights or other proprietary rights.

b) All rights, title and interest in and to certain inventions, ideas, designs and methods, specifications and other documentation related thereto developed by the Agency and its subAgencys specifically for the County, hereinafter referred to as "Developed Works" shall become the property of the County.

c) Accordingly, neither the Agency nor its employees, agents, subAgencys or suppliers shall have any proprietary interest in such Developed Works. The Developed Works may not be utilized, reproduced or distributed by or on behalf of the Agency, or any employee, agent, subAgency or supplier thereof, without the prior written consent of the County, except as required for the Agency's performance hereunder.

d) Except as otherwise provided in subsections a, b, and c above, or elsewhere herein, the Agency and its subAgencys and suppliers hereunder shall retain all proprietary rights in and to all Licensed Software provided hereunder, that have not been customized to satisfy the performance criteria set forth in the Scope of Services. Notwithstanding the foregoing, the Agency hereby grants, and shall require that its subAgencys and suppliers

grant, if the County so desires, a perpetual, irrevocable and unrestricted right and license to use, duplicate, disclose and/or permit any other person(s) or entity(ies) to use all such Licensed Software and the associated specifications, technical data and other Documentation for the operations of the County or entities controlling, controlled by, under common control with, or affiliated with the County, or organizations which may hereafter be formed by or become affiliated with the County. Such license specifically includes, but is not limited to, the right of the County to use and/or disclose, in whole or in part, the technical documentation and Licensed Software, including source code provided hereunder, to any person or entity outside the County for such person's or entity's use in furnishing any and/or all of the Deliverables provided hereunder exclusively for the County or entities controlling, controlled by, under common control with, or affiliated with the County, or organizations which may hereafter be formed by or become affiliated with the County. No such License Software, specifications, data, documentation or related information shall be deemed to have been given in confidence and any statement or legend to the contrary shall be void and of no effect.

ARTICLE 31. INSPECTOR GENERAL REVIEWS

Independent Private Sector Inspector General Reviews

Pursuant to Miami-Dade County Administrative Order 3-20, the County has the right to retain the services of an Independent Private Sector Inspector General (hereinafter "IPSIG"), whenever the County deems it appropriate to do so. Upon written notice from the County, the Agency shall make available to the IPSIG retained by the County, all requested records and documentation pertaining to this Agreement for inspection and reproduction. The County shall be responsible for the payment of these IPSIG services, and under no circumstance shall the Agency's prices and any changes thereto approved by the County, be inclusive of any charges relating to these IPSIG services. The terms of this provision herein, apply to the Agency, its officers, agents, employees, subAgencys and assignees. Nothing contained in this provision shall impair any independent right of the County to conduct an audit or investigate the operations, activities and performance of the Agency in connection with this Agreement. The terms of this Article shall not impose any liability on the County by the Agency or any third party.

Miami-Dade County Inspector General Review

According to Section 2-1076 of the Code of Miami-Dade County, as amended by Ordinance No. 99-63, Miami-Dade County has established the Office of the Inspector General which may, on a random basis, perform audits on all County contracts, throughout the duration of said contracts, except as otherwise provided below. The cost of the audit for this Contract shall be one quarter (1/4) of one (1) percent of the total contract amount which cost shall be included in the total contract amount. The audit cost will be deducted by the County from progress payments to the Agency. The audit cost shall also be included in all change orders and all contract renewals and extensions.

Exception: The above application of one quarter (1/4) of one percent fee assessment shall not apply to the following contracts: (a) IPSIG contracts; (b) contracts for legal services; (c) contracts for financial advisory services; (d) auditing contracts; (e) facility rentals and lease agreements; (f) concessions and other rental agreements; (g) insurance contracts; (h) revenue-generating contracts; (i) contracts where an IPSIG is assigned at the time the contract is approved by the Commission; (j) professional service agreements under $1,000; (k) management agreements; (l) small purchase orders as defined in Miami-Dade County

Administrative Order 3-2; (m) federal, state and local government-funded grants; and (n) interlocal agreements. ***Notwithstanding the foregoing, the Miami-Dade County Board of County Commissioners may authorize the inclusion of the fee assessment of one quarter (1/4) of one percent in any exempted contract at the time of award.***

Nothing contained above shall in any way limit the powers of the Inspector General to perform audits on all County contracts including, but not limited to, those contracts specifically exempted above. The Miami-Dade County Inspector General is authorized and empowered to review past, present and proposed County and Public Health Trust contracts, transactions, accounts, records and programs. In addition, the Inspector General has the power to subpoena witnesses, administer oaths, require the production of records and monitor existing projects and programs. Monitoring of an existing project or program may include a report concerning whether the project is on time, within budget and in conformance with plans, specifications and applicable law. The Inspector General is empowered to analyze the necessity of and reasonableness of proposed change orders to the Contract. The Inspector General is empowered to retain the services of independent private sector inspectors general (IPSIG) to audit, investigate, monitor, oversee, inspect and review operations, activities, performance and procurement process, including but not limited to project design, specifications, proposal submittals, activities of the Agency, its officers, agents and employees, lobbyists, County staff and elected officials to ensure compliance with contract specifications and to detect fraud and corruption.

Upon written notice to the Agency from the Inspector General or IPSIG retained by the Inspector General, the Agency shall make all requested records and documents available to the Inspector General or IPSIG for inspection and copying. The Inspector General and IPSIG shall have the right to inspect and copy all documents and records in the Agency's possession, custody or control which, in the Inspector General's or IPSIG's sole judgment, pertain to performance of the contract, including, but not limited to original estimate files, change order estimate files, worksheets, proposals and agreements form and which successful and unsuccessful subAgencys and suppliers, all project-related correspondence, memoranda, instructions, financial documents, construction documents, proposal and contract documents, back-charge documents, all documents and records which involve cash, trade or volume discounts, insurance proceeds, rebates, or dividends received, payroll and personnel records, and supporting documentation for the aforesaid documents and records.

ARTICLE 32. LOCAL, STATE, AND FEDERAL COMPLIANCE REQUIREMENTS

Agency agrees to comply, subject to applicable professional standards, with the provisions of any and all applicable Federal, State and the County orders, statutes, ordinances, rules and regulations which may pertain to the Services required under this Agreement, including but not limited to:

a) Equal Employment Opportunity (EEO), in compliance with Executive Order 11246 as amended and applicable to this Contract.

b) Miami-Dade County Florida, Department of Small Business Development Participation Provisions, as applicable to this Contract.

c) Environmental Protection Agency (EPA), as applicable to this Contract.

d) Miami-Dade County Code, Chapter 11A, Article 3. All Agencys and subAgencys performing work in connection with this Contract shall provide equal opportunity for

employment because of race, religion, color, age, sex, national origin, sexual preference, disability or marital status. The aforesaid provision shall include, but not be limited to, the following: employment, upgrading, demotion or transfer, recruitment advertising; layoff or termination; rates of pay or other forms of compensation; and selection for training, including apprenticeship. The Agency agrees to post in conspicuous place available for employees and applicants for employment, such notices as may be required by the Dade County Fair Housing and Employment Commission, or other authority having jurisdiction over the work setting forth the provisions of the nondiscrimination law.

e) "Conflicts of Interest" Section 2-11 of the County Code, and Ordinance 01-199.

f) Miami-Dade County Code Section 10-38 "Debarment".

g) Miami-Dade County Ordinance 99-5, codified at 11A-60 et. seq. of Miami-Dade Code pertaining to complying with the County's Domestic Leave Ordinance.

h) Miami-Dade County Ordinance 99-152, prohibiting the presentation, maintenance, or prosecution of false or fraudulent claims against Miami-Dade County.

Notwithstanding any other provision of this Agreement, Agency shall not be required pursuant to this Agreement to take any action or abstain from taking any action if such action or abstention would, in the good faith determination of the Agency, constitute a violation of any law or regulation to which Agency is subject, including but not limited to laws and regulations requiring that Agency conduct its operations in a safe and sound manner.

ARTICLE 33. NONDISCRIMINATION

During the performance of this Contract, Agency agrees to not discriminate against any employee or applicant for employment because of race, religion, color, sex, handicap, marital status, age or national origin, and will take affirmative action to ensure that they are afforded equal employment opportunities without discrimination. Such action shall be taken with reference to, but not limited to: recruitment, employment, termination, rates of pay or other forms of compensation, and selection for training or retraining, including apprenticeship and on the job training.

By entering into this Contract, the Agency attests that it is not in violation of the Americans with Disabilities Act of 1990 (and related Acts) or Miami-Dade County Resolution No. R-385-95. If the Agency or any owner, subsidiary or other firm affiliated with or related to the Agency is found by the responsible enforcement agency or the County to be in violation of the Act or the Resolution, such violation shall render this Contract void. This Contract shall be void if the Agency submits a false affidavit pursuant to this Resolution or the Agency violates the Act or the Resolution during the term of this Contract, even if the Agency was not in violation at the time it submitted its affidavit.

ARTICLE 34. CONFLICT OF INTEREST

The Agency represents that:

a) No officer, director, employee, agent, or other consultant of the County or a member of

the immediate family or household of the aforesaid has directly or indirectly received or been promised any form of benefit, payment or compensation, whether tangible or intangible, in connection with the grant of this Agreement.

b) There are no undisclosed persons or entities interested with the Agency in this Agreement. This Agreement is entered into by the Agency without any connection with any other entity or person making a proposal for the same purpose, and without collusion, fraud or conflict of interest. No elected or appointed officer or official, director, employee, agent or other consultant of the County, or of the State of Florida (including elected and appointed members of the legislative and executive branches of government), or a member of the immediate family or household of any of the aforesaid:

i) is interested on behalf of or through the Agency directly or indirectly in any manner whatsoever in the execution or the performance of this Agreement, or in the services, supplies or work, to which this Agreement relates or in any portion of the revenues; or

ii) is an employee, agent, advisor, or consultant to the Agency or to the best of the Agency's knowledge any subAgency or supplier to the Agency.

c) Neither the Agency nor any officer, director, employee, agency, parent, subsidiary, or affiliate of the Agency shall have an interest which is in conflict with the Agency's faithful performance of its obligation under this Agreement; provided that the County, in its sole discretion, may consent in writing to such a relationship, provided the Agency provides the County with a written notice, in advance, which identifies all the individuals and entities involved and sets forth in detail the nature of the relationship and why it is in the County's best interest to consent to such relationship.

d) The provisions of this Article are supplemental to, not in lieu of, all applicable laws with respect to conflict of interest. In the event there is a difference between the standards applicable under this Agreement and those provided by statute, the stricter standard shall apply.

e) In the event Agency has no prior knowledge of a conflict of interest as set forth above and acquires information which may indicate that there may be an actual or apparent violation of any of the above, Agency shall promptly bring such information to the attention of the County's Project Manager. Agency shall thereafter cooperate with the County's review and investigation of such information, and comply with the instructions Agency receives from the Project Manager in regard to remedying the situation.

ARTICLE 35. PRESS RELEASE OR OTHER PUBLIC COMMUNICATION

Under no circumstances shall the Agency without the express written consent of the County:

a) Issue or permit to be issued any press release, advertisement or literature of any kind which refers to the County, or the Work being performed hereunder, unless the Agency first obtains the written approval of the County. Such approval may be withheld if for any reason the County believes that the publication of such information would be harmful to the public interest or is in any way undesirable; and

b) Communicate in any way with any Agency, department, board, agency, commission or other organization or any person whether governmental or private in connection with the Services to be performed hereunder except upon prior written approval and instruction of

the County; and

c) Except as may be required by law, the Agency and its employees, agents, subAgencys and suppliers will not represent, directly or indirectly, that any product or service provided by the Agency or such parties has been approved or endorsed by the County.

ARTICLE 36. BANKRUPTCY

The County reserves the right to terminate this contract, if, during the term of any contract the Agency has with the County, the Agency becomes involved as a debtor in a bankruptcy proceeding, or becomes involved in a reorganization, dissolution, or liquidation proceeding, or if a trustee or receiver is appointed over all or a substantial portion of the property of the Agency under federal bankruptcy law or any state insolvency law.

ARTICLE 37. GOVERNING LAW

This Contract, including appendices, and all matters relating to this Contract (whether in contract, statute, tort (such as negligence), or otherwise) shall be governed by, and construed in accordance with, the laws of the State of Florida. Venue shall be Miami-Dade County.

ARTICLE 38. INDIVIDUALLY IDENTIFIABLE HEALTH INFORMATION and/or PROTECTED HEALTH INFORMATION

Any person or entity that performs or assists Miami-Dade County with a function or activity involving the use or disclosure of "Individually Identifiable Health Information (IIHI) and/or Protected Health Information (PHI) shall comply with the Health Insurance Portability and Accountability Act (HIPAA) of 1996 and the Miami-Dade County Privacy Standards Administrative Order. HIPAA mandates for privacy, security and electronic transfer standards, include but are not limited to:

1. Use of information only for performing services required by the contract or as required by law;
2. Use of appropriate safeguards to prevent non-permitted disclosures;
3. Reporting to Miami-Dade County of any non-permitted use or disclosure;
4. Assurances that any agents and subAgencys agree to the same restrictions and conditions that apply to the Agency and reasonable assurances that IIHI/PHI will be held confidential;
5. Making Protected Health Information (PHI) available to the customer;
6. Making PHI available to the customer for review and amendment; and incorporating any amendments requested by the customer;
7. Making PHI available to Miami-Dade County for an accounting of disclosures; and
8. Making internal practices, books and records related to PHI available to Miami-Dade County for compliance audits.

PHI shall maintain its protected status regardless of the form and method of transmission (paper records, and/or electronic transfer of data). The Agency must give its customers written notice of its privacy information practices including specifically, a description of the types of uses and disclosures that would be made with protected health information.

ARTICLE 39. SURVIVAL.

The parties acknowledge that any of the obligations in this Agreement will survive the term, termination and cancellation hereof. Accordingly, the respective obligations of the Agency and the County under this Agreement, which by nature would continue beyond the termination, cancellation or expiration thereof, shall survive termination, cancellation or expiration hereof.

IN WITNESS WHEREOF, the parties have executed this Agreement effective as of the contract date herein above set forth.

Agency	Miami-Dade County
By: _____	By: _____
Name: Carlos A. Alvarez	Name: _____
Title: President & CEO	Title: _____
Date: 11/3/11	Date: _____
Attest: _____	Attest: _____
Corporate Secretary/Notary Public	Clerk of the Board
Lillian Horsley Hance	
Corporate Seal/Notary Seal	Approved as to form and legal sufficiency
	_____
	Assistant County Attorney

LILLIAN HORSLEY HANCE
COMMISSION # DD 913356
EXPIRES: November 3, 2013
Bonded Thru Notary Public Underwriters

APPENDIX A

Scope of Services- Employee Testing & Medical Assessment Services

1. INTRODUCTION/BACKGROUND

Miami-Dade County, hereinafter referred to as the County, as represented by the Human Resources Department, is contracting for a qualified medical provider to perform a variety of occupational health services in the areas of pre-employment physical examinations for applicants, high stress physical examinations for employees within designated classifications, and fitness for duty examinations and required drug and alcohol testing assessments for current employees in accordance with the established protocols.

2. MINIMUM REQUIREMENTS

A. Contractor's physicians performing Services shall be licensed practitioners by the State of Florida, Department of Health, Division of Medical Quality Assurance.

B. Contractor's facilities utilized to provide the Services shall be licensed by the State of Florida, Agency for Health Care Administration.

3. SERVICES TO BE PROVIDED

The Contractor shall:

3.1 Conduct, in accordance with Miami-Dade County's Employee Medical Assessment and Testing Procedures Protocols (Appendix D), as applicable: 1) pre-employment physical examinations for applicants, 2) high stress physical examinations for designated classifications and 3) fitness for duty examinations and required drug and alcohol screening testing for current employees.

A, A-1. Miami-Dade County's Employee Medical Assessment and Testing Procedures - Standard and Modified Pre-employment Physical Examination Procedures;

B. Miami-Dade County's Employee Medical Assessment and Testing Procedures - High Stress Physical Examination Procedures;

C. Miami-Dade County Scientific and Administrative Protocol for the Alcohol and Drug Abuse Workplace Policy;

D. Miami-Dade County's Employee Medical Assessment and Testing Procedures - Fitness for Duty Physical Examination;

E. Medical Monitoring and Exposure Testing as Required by OSHA;

F. Department of Transportation's Drug and Alcohol Testing Programs;

F-1. Procedures for Transportation Workplace Drug and Alcohol Testing Programs *(Title 49 CFR Part 40)*;

F-2. Prevention of Alcohol Misuse and Prohibited Drug Use in Transit Operations *(Title 49 CFR Part 655)*; and

F-3. Controlled Substances and Alcohol Use and Testing *(Title 49 CFR Part 382)*.

3.2 Perform medical examination and assessment services by Board Certified Internal Medicine or Family Practice State of Florida licensed physicians. Both male and female physicians shall be available to perform such examinations upon the examinees' specific request.

3.3 Conduct all appointments for **pre-employment physical examinations** between the hours of 8:00 a.m. - 5:00 p.m., Monday through Friday. The County may request that appointments be conducted on Saturday, when deemed necessary by the County.

3.4 Conduct all appointments for **high stress physical examinations** in two phases (two visits). Appointments for Phase I shall be conducted during the early morning hours of 7:00 a.m.-10:00 a.m., Monday through Friday to limit examinees' fasting time. The County may request that Phase I appointments be conducted on Saturday, if deemed necessary. The second phase (Phase II) shall be conducted no later than 3 days after completion of the Phase I, between the hours of 8:00 a.m. - 5:00 p.m., Monday through Friday. The Contractor shall be assessed liquidated damages in the amount of $25.00 per examinee who arrives within 10 minutes of their scheduled appointment time and is kept waiting for 30 minutes or longer.

3.5 Perform all appointments for **fitness for duty physical examinations** within 2 days of appointment confirmation by the County. A narrative report of the findings and recommendations of the examination shall be electronically forwarded by the Contractor to the County's Project Manager within 5 business days from completion of the examination. The Contractor shall be assessed liquidated damages in the amount of $100.00 per day, for fitness for duty reports received later than 5 business days from completion of the examination.

3.6 Operate at least one facility that is open and fully operational 24 hours a day, with the capacity of performing any of the physical examinations and testing services listed herein in accordance with the established protocols. Such facility shall also have the capacity, in case of emergency, to administer a complete High Stress Physical Examination; both Phase I and II, in a single appointment. Such emergency appointments must be authorized by County's Program Manager.

3.7 Render certified Medical Review Officer's (MRO) services as specified in the established protocol documents. The MRO shall be a licensed physician (Medical Doctor or Doctor of Osteopathy) responsible for reviewing laboratory results generated by applicants and examinees referred by the County, who has specific knowledge of substance abuse disorders and appropriate medical training to interpret and evaluate an examinee's confirmed positive test results together with medical history and any other relevant biomedical information. Additionally, the MRO shall be available to provide technical guidance to County staff and expert testimony at any formal proceeding where it may be necessary. The County prefers that 2 MROs be available to render services to the County for continuity of services and efficiencies. All MRO consultations shall be conducted in person, Monday-Friday between the hours of 8:00 a.m. – 5 p.m., unless otherwise requested or approved by the County. MROs providing the services shall be certified and trained in accordance with current Department of Transportation (DOT) regulations (Title 49 CFR Part 40).

3.8 Interpret all X-ray and EKG results utilizing Board Certified specialists (i.e., cardiologist, radiologist (to include B Reader), etc.).

3.9 Complete the re-examination and/or re-testing of employees/applicants who are recommended by Contractor's physician to be temporarily deferred from commencing employment or returning to work, at no additional charge to the County or employee/applicant.

3.10 Facilitate medical reviews by an independent third party, when deemed necessary and as requested by the County, to resolve matters that require a second opinion. The independent third party shall offer a variety of medical services to include: Cardiology, Endocrinology, Gastroenterology, Hematology, Immunology, Oncology, Ophthalmology, Psychiatry, Pulmonology, Neurology and Radiology. Contractor must gain prior approval from the County's Project Manager for authorization of medical services to be rendered by third party. The Contractor shall pay the third party and then invoice the County for the approved services in its monthly itemized invoice to include supporting documentation. The County will reimburse the Contractor for the services rendered by the third party, upon review and approval of itemized invoice.

3.11 Administer the collection of all drug and alcohol screening testing in strict compliance with the established procedures and protocols set forth in the referenced documents. All Breath Alcohol Technicians (BAT) conducting collection services shall be certified and trained in accordance with current DOT regulations (Title 49 CFR Part 40). (Note: The County reserves the right to conduct unannounced protocol compliance inspections at any time.)

3.12 Provide secure area for specimen collection within Contractor's facilities. County applicants and employees required to provide specimens shall have minimal contact with other patients and staff at Contractor's facilities.

3.13 Collect all urine specimens utilizing the standard Urine Collection Kits which contain a collection container, plastic specimen bottles, leak-resistant plastic bag, absorbent material and shipping container.

3.14 Perform on-site specimen collection and medical services 24 hours, 7 days a week on an as needed basis, but no later than within 3 days of County's request. On-site collections shall be performed at a County designated facility or via Contractor's Mobile Unit, if available. The selection of the type of on-site service is entirely at the discretion of the County. Mobile Unit shall be self-contained to ensure examinees' privacy, include a urinal, sink, running water, storage areas with the capacity to store collected samples at proper temperature.

All laboratories utilized for drug and alcohol testing, as stipulated in the established protocol documents, require County approval. The Contractor shall submit specimen collected to labs for testing. The Contractor shall pay the labs for the specimen testing services rendered. Charges for the collection, transportation of specimen, testing and the reporting of results are included in the cost of the respective physical examination. The County reserves the right to approve or disapprove (i.e., add or delete) the laboratories.

3.15 Perform medical monitoring and exposure testing *(medical evaluations and/or tests related to hazardous exposure and safety issues)* in accordance with established protocols. Services may be performed at Contractor's facilities or onsite at the employees' jobsite location, as deemed necessary and scheduled by the County.

3.16 Allow the County and its authorized personnel to perform new hire applicant fingerprinting and administrative processing functions at Contractor's facilities, as deemed

necessary by the County and with the accord of the Contractor.

3.17 Provide individual, secure storage lockers at each of the Contractor's facilities, for the use of all examinees. Secure storage lockers should include individual compartment (not shared amongst several examinees) where examinee can place personal belongings and lock with a key that is maintained by the examinee.

3.18 Assist the County in resolving medically related employment issues to include, but not be limited to, American with Disabilities Act (ADA) and Family Medical Leave Act (FMLA) matters, as necessary and requested by the County, in addition to, redesigning forms and updating protocols and procedures.

4. ADMINISTRATIVE and RELATED SERVICES

The Contractor shall perform the following administrative services:

4.1 Designate a Project Manager who shall serve as liaison between the County and the Contractor on all matters relating to the services listed herein. Designated Project Manager shall be responsible for, and coordinate the functions of, all of Contractor's facilities approved for Services by the County.

4.2 Complete implementation of the Services within thirty (30) days after award. The Contractor will submit for County approval the implementation schedule immediately upon contract execution to allow for the acquisition, installation, configuration, and testing of all equipment to be utilized in rendering the services listed herein.

4.3 Ensure that facilities utilized to provide the Services have the required materials and equipment necessary to conduct physical examinations and drug and alcohol screening tests in accordance with the established protocols. The Contractor shall ensure staff levels necessary to perform the Services listed herein, in addition to, the acquisition, installation, configuration and maintenance of all office equipment and supplies.

4.4 Ensure the maintenance and calibration of the equipment utilized at each facility. All Evidential Breath Testing Devices (i.e., the Intoximeter's Alcomonitor CC) shall be approved by the National Highway Traffic Safety Administration (NHTSA) and automatically generate documented results. The County may require establishing scheduled maintenance intervals for Contractor's equipment utilized in rendering services listed herein, at its sole discretion.

4.5 Ensure Contractor's facilities offer adequate parking *(at no charge)* and reception area staff to accommodate all scheduled examinees. The facilities shall be clean and located in a safe area.

4.6 Mail individual results letter directly to respective employees' home address specifying the results of the physical examination, abnormalities and physician's recommendations to include all laboratory results within 7 days of Phase II of the High Stress Physical Examination.

4.7 Conform to the County's data processing requirements and interface with administrative and reporting systems. The Contractor shall access the County's Human Resources Department electronic systems' daily to query and identify appointments and transmit the Work Status Report and drug screening testing results to the County's Medical Records Application. Application level training will be provided to the Contractor by the County.

The hardware and software required for this transmission includes the following:

a. Windows PC with Internet Explorer;
b. Internet Connection;
c. Citrix Active X or any other County approved client software to connect to the County network; and
d. Secure File Transfer Protocol (FTP)

4.8 Perform data-entry functions to record the results of the physical examinations and any related pertinent information as required by the County's Medical Records Application.

4.9 Transmit to the County's Project Manager confirmed positive drug and alcohol screening results completed by the toxicology laboratory electronically utilizing the County's Medical Records Application secure FTP on the same day the results are received by the Contractor.

4.10 Transmit to the County's Project Manager the physical examination results electronically utilizing the County's Medical Records Application secure FTP within 3 business days from the initial appointment date. If results cannot be entered within 3 days due to pending lab work or required retests, the County's Project Manager shall be notified of the reason for the delay and the anticipated completion date. No-show appointments shall be entered into the information system daily.

The electronic documents being transmitted to the County shall be formatted using the mass scan batch (MSB) process. The MSB is a format which contains document index information as well as the path to the electronic document file associated with the indexes. The MSB may contain references to several documents and examinees. The Contractor may determine how many electronic documents to include within each MSB file transmitted to the County. Since MSB is a text file, the medical documents shall be either in the Tagged Image File Format (TIFF) or Portable Document Format (PDF) document type. The County will not offer Virtual Private Network (VPN) access, however the transmission utilized to transport the medical records across public networks to the County shall be secure.

4.11 Perform quality assurance level review comparing the paper/form recorded results with those initially entered, prior to transmission. The County will also conduct quality assurance reviews, at its sole discretion, to ensure the integrity of the results entered by the Contractor. The County will notify the Contractor of any integrity discrepancy for immediate corrective action. The Contractor shall perform any and all necessary work to rectify the matter. At no time shall a correction exceed 7 business days from notification, unless otherwise approved by the County.

4.12 Submit entire and completed Physical Examination and Drug/Alcohol Results Package electronically to the County's Project Manager no later than 2 weeks from the date the Contractor first sends the physical examination results.

Package includes all laboratory reports and County required forms as listed below:

i) Physical Examination and Drug/Alcohol Screen Appointment Schedule;
ii) Statement of Authorization;
iii) Drug/Alcohol Usage Analysis Consent and Release Form;
iv) Work Status Report;
v) Specimen Collection Checklist and Chain of Custody;

vi) Medical History Statement;
vii) Doctor's Report;
viii) Laboratory Reports; and
ix) Toxicology Submission Form and Analysis Report

All forms in package shall be completed and signed by the licensed physician conducting examination and laboratory staff completing specimen collection and testing, as indicated.

All required forms shall initially be provided to the Contractor by the County for reproductions and subsequent presentation to each examinee at time of scheduled appointment, unless provisions are made by the County to provide the forms directly to the examinee prior to the scheduled appointment. The County reserves the right to modify or change the forms as necessary.

4.13 Prepare and submit any other report as required by the County, State or Federal agencies which contains information generally found in the Physical Examination Results Package (e.g., Florida Criminal Justice Standards and Training Commission Minimum Guidelines for Physical Examination Doctor's Report for police and correction, and the Bureau of Fire Standards and Training Medical Examination Form for firefighters).

4.14 Maintain records indicating examinees' name, date of examination, and identification of examination and tests performed. Such information shall be available at the facility where physical examination was conducted for review by the County at any time. In addition, the Contractor shall maintain a complete file of each examinee for at least 5 years from the date of the completed physical examination. Such records shall be made available to the County within 48 hours of request. All provisions listed herein shall be monitored by the County for strict compliance and enforcement purposes.

4.15 Comply with Chapter 119 of the Florida Statutes with regards to the inspection, copying maintenance, and disposition of records which do not violate Federal Regulations regarding HIPAA compliance or other applicable Florida Statues. Any and all requests for inspection or copies of documents and/or files in the Contractor's possession, made by a party other than the County's Project Manager, shall be forwarded to the County in writing for processing. At no time shall the Contractor provide access to records in their possession without prior written approval by the County's Project Manager. In an effort to increase efficiency, responsiveness, and further environmental efforts, electronic (digital) records are acceptable media substitute for "hard copy" paper and shall be pursued as an option of choice to achieve compliance. Where electronic (digital) formats exists of these records it shall be used to transmit the data, file, report, document, picture, or any other object that may be available in an electronic (digital) format. Electronic records shall be kept in industry standard formats: TIFF or Adobe PDF. Electronic signatures are also acceptable to ensure compliance. Acceptable formats include the use of User ID/Password, Personal Identification Number (PIN), and key encryption. Any other method shall require written approved by the County prior to acceptance.

4.16 The Contractor shall self report to the County their fulfillment with the requirements of Sections 3.4 and 3.5 (which are subject to liquidated damages) on a monthly basis utilizing data gathered. The report shall be provided to the County along with the applicable invoice for the period covered. Any payments due to the County in accordance with those liquidated damages provisions shall be deducted from the Contractor's itemized invoice for said month. The Contractor's reporting may be subject to an audit at the County's discretion.

5. ADDITIONAL SERVICES

The Contractor shall perform the following additional services not associated with physical examinations, at no additional cost.

5.1 Conduct County approved satisfaction survey of referred examinees on a continuing basis. The Contractor shall report results of survey on a quarterly basis to the County.

5.2 Conduct quarterly educational workshops and provide educational materials on various health topics at County worksites for the benefit of County employees, subject to County approval.

5.3 Provide technical assistance to the County's Wellness Program. The County's Wellness Program is designed to increase awareness and encourage employees and their families to pursue health conscious habits.

6. OPTIONAL TESTING

At the County's sole discretion, the County may require the Contractor to provide optional testing on an "as needed basis" in accordance with Price Schedule, Appendix B.

APPENDIX B

Price Schedule – Employee Testing & Medical Assessment Services

The following are the rates to provide the Employee Testing & Medical Assessment Services which include all services specified in the Scope of Services (Appendix A) in accordance with the table below.

A. RATES

1. PRE-EMPLOYMENT PHYSICAL EXAMINATIONS

Examination	Rate (per applicant)
Standard Pre-Employment Physical Examination ***(See Appendix D, Protocol A)***	$ 58.00
Modified Pre-Employment Physical Examination ***(See Appendix D, Protocol A-1)***	$ 35.00

2. HIGH STRESS PHYSICAL EXAMINATIONS

Examination	Rate (per examinee)
High Stress Physical Examination *(includes Phase I & II, excluding treadmill stress, mammogram and body scan tests)* ***(See Appendix D, Protocol B)***	$ 95.00

Notes:

1. All rates shall be guaranteed for the initial contract term.
2. Contractor shall be paid for actual testing authorized and performed. The County makes no representations or guarantees of the number of applicants or examinees.
3. All out-of-pocket expenses, including materials, and miscellaneous costs and fees, are included in the rates, as they shall not be reimbursed separately by the County.
4. The rates are all-inclusive; no add-on charges for services are allowed.
5. The County will reimburse the Contractor for the approved third party services per Section 3.10 (See Appendix A).
6. The Contractor shall provide written notification and justification to the County within twelve (12) months of the Contract expiration date of any proposed increase in the physical examination rates for the option to renew period. Contractor shall base any proposed rate increase on operational costs and shall submit to the County the Contractor's methodology used to determine the new rates. Supporting utilization data, adherence to turnaround reporting requirements as specified in Appendix A and customer satisfaction results shall also be provided for the first four contract years to facilitate the County's renewal process. If no recommended increase is received by the set date, the rates shall remain the same for the two year option period. Any agreed upon rate increase shall not exceed 2% in the aggregate for Optional Years 2017 and 2018.

B. Optional Testing, As Necessary

The Contractor's rates for providing optional testing in accordance with Appendix A, Scope of Services and applicable Protocols thereto shall include all expenses associated with the task. All rates are fixed for the initial contract term and any option to renew period. Optional testing may be requested on an as needed basis at the County's sole discretion.

1. Pre-employment Examination – Optional Testing Services	Rate
Specimen Collection for Drug Testing Only:	
a. Urine	$ 5.00
b. Breath-Alcohol	$ 5.00
c. Blood	$ 5.00
Urinalysis Drug Testing (Lab Work Only)	$ 20.00
Physicians Re-evaluation (Without Labs)	$ 10.00
Medical History Review (With Labs)	$ 30.00
Medical Review Officer – Charge per Month	$ 375.00
Urinalysis	$ 12.00
Vision Test	$ 5.00
Pulmonary Function Test	$ 18.00
Hearing Check	$ 5.00
PPD Test	$ 5.00
Audiogram	$10.00
Chest X-Ray	$ 25.00
Tetanus Inoculation	$ 20.00
Typhoid Inoculation	$ 79.00
Mobile Unit (per day)	$ 895.00
Expert Testimony Fees:	
a. Certified Technician	$ 47.00 per hour(1)
b. Forensic Toxicologist - Unemployment Hearing	$ 300.00 per hour(1)
c. Forensic Toxicologist - Termination Hearing	$ 300.00 per hour(1)
d. Forensic Toxicologist - Litigation Package	$ 375.00 per hour(1)

2. High Stress Examination – Optional Testing Services	Rate
Specimen Collection for Drug Testing Only: a. Urine	$ 5.00
b. Breath – Alcohol	$ 5.00
c. Blood	$ 5.00
Urinalysis Drug Testing (Laboratory Work Only)	$ 20.00
Lead Level Blood Test	$ 25.00
Hemoglobin A1c	$ 15.00
Urinalysis	$ 12.00
Urine Manganese Test	$ 90.00
Vision Test	$ 5.00
Pulmonary Function Test	$ 18.00
Audiometric Testing/Evaluation	$ 20.00
PPD Test	$ 5.00
Audiogram	$ 10.00
Chest X-Ray	$ 25.00
Tetanus Inoculation	$ 20.00
Typhoid Inoculation	$ 79.00
Hepatitis A Screen	$ 32.00
Fitness for Duty Physical per Appendix D – Protocol D (Independent Medical Evaluation)	$ 60.00
Medical Review Officer – Charge per Month	$ 375.00
Special Eye Examination	$ 155.00
Pulmonary Function Test with FVC & FEV 1	$ 18.00
Medical Surveillance Medical Evaluation per Appendix D – Protocol E	$ 30.00
Hazmat Testing	$ 75.00
Heavy Metal Testing	$ 50.00
Cholenesterease Testing	$ 25.00
Lead and Zinc Protoporphyrin Testing	$ 65.00
Zinc Protoporphyrin Testing	$ 45.00
PSA Test	$ 20.00
Hepatitis B Vaccine	$ 69.00
Hepatitis B Titer	$ 15.00
Hepatitis A Vaccine	$ 75.00
Hepatitis A Titer	$ 32.00
HIV Screening	$ 30.00
Blood Gas Testing	$ 35.00
Post Exposure Consultation/Evaluation per Appendix D – Protocol E	$ 25.00
Hepatitis C Screening	$ 15.00
Measles, Mumps, Rubella Immunization	$ 78.00
Thyroid Profile	$ 40.00
Rubella Titer	$ 15.00
Rubella Immunization	$ 78.00
Mammogram	$ 160.00

High Stress Examination – Optional Testing Services (Cont'd)

Comprehensive Hearing Test	$ 20.00
Cardiovascular Stress Test:	
a. Echocardiogram	$ 300.00
b. Thallium Stress	$ 980.00
c. Exercise Muga Stress	$ 450.00
Radiological Evaluation (Chest X-Ray)	$ 25.00
Full Body Scan (Shoulders to Upper Thigh) CT Scan/ Ultrasound	$ 900.00/ $459.00
Partial Body Scan 1 (Chest) CT Scan / Ultrasound	$ 300.00/ $153.00
Partial Body Scan 2 (Abdomen) CT Scan / Ultrasound	$ 300.00/ $153.00
Partial Body Scan 3 (Pelvic) CT Scan / Ultrasound	$ 300.00/ $153.00
Flexible Sigmoidoscopy	$ 375.00
Colonoscopy	$ 980.00
Treadmill Stress Test (Phase II) per Appendix D - Protocol B	$ 250.00
RPR	$ 10.00
Flu Shot	$ 25.00
Pregnancy Test	$ 10.00
FAA (Physical Examination)	$ 100.00
Tetanus Booster	$ 20.00
PSA	$ 20.00
CA 125	$ 18.00
Blood Type & Rh Typing	$ 20.00
Review & Written Interpretation of Medical Records	$ 25.00
Psychiatric Consultation	$ 175.00
Anti-HBS/HBSAG	$ 20.00
Recombivax x 1	$ 69.00
Recombivax x 3	$ 207.00
Rabies	$ 400.00
Echo Doppler	$ 300.00
EKG (12 lead)	$ 35.00
Stress Thallium	$ 980.00
EEG	$ 100.00
Upper G.I.	$ 165.00
24-Hour Avionics	$ 175.00
Sed Rate	$ 5.00
Glaucoma	$ 5.00
Iron and BC Serum	$ 12.00
Ferrutin Level Serum	$ 6.00
Sput AFB Smear	$ 6.00
Sput AFB Culture	$ 10.00
Back Evaluation	$ 30.00
Mobile Unit (per day)	$ 895.00
Expert Testimony Fees:	
a. Certified Technician	$ 47.00 per hour(1)
b. Forensic Toxicologist - Unemployment Hearing	$ 300.00 per hour(1)
c. Forensic Toxicologist - Termination Hearing	$ 300.00 per hour(1)
d. Forensic Toxicologist - Litigation Package	$ 375.00 per hour(1)

Notes:

1. The hourly rates include all out-of-pocket expenses, including materials, employee travel, per diem, and miscellaneous costs and fees, as any expenses shall not be reimbursed separately by the County.
2. Contractor's physicians may medically prescribe as part of the High Stress Physical Examination, for classifications identified by the County.

APPENDIX C

HIPAA BUSINESS ASSOCIATE ADDENDUM

This HIPAA Business Associate Addendum ("Addendum") supplements and is made a part of the Agreement by and between the Miami-Dade County, Florida ("County"), and Jackson Health System ("Associate").

RECITALS

A. As part of the Agreement, it is necessary for the County to disclose certain information ("Information") to Associate pursuant to the terms of the Agreement, some of which may constitute Protected Health Information ("PHI").

B. County and Associate intend to protect the privacy and provide for the security of PHI, including but not limited to, ePHI, disclosed to Associate pursuant to the Agreement in compliance with the Health Insurance Portability and Accountability Act of 1996, Public Law 104-191 ("HIPAA") and regulations promulgated thereunder by the U.S. Department of Health and Human Services (the "HIPAA Regulations") and other applicable laws.

C. The purpose of this Addendum is to satisfy certain standards and requirements of HIPAA and the HIPAA Regulations, including, but not limited to, Title 45, Sections 164.308(b), 164.314(a), 164.502(e) and 164.504(e) of the Code of Federal Regulations ("CFR"'), as the same may be amended from time to time.

In consideration of the mutual promises below and the exchange of information pursuant to the Agreement, the parties agree as follows:

1. **Definitions.** Terms used, but not otherwise defined, shall have the same meaning as those terms in 45 CFR Sections 160.103, 164.304 and 164.501.

a. "Business Associate" shall have the meaning given to such term under the HIPAA Regulations, including, but not limited to, 45 CFR Section 160.103.

b. "Covered Entity" shall have the meaning given to such term under HIPAA and the HIPAA Regulations, including, but not limited to, 45 CFR Section 160.103.

c. "Protected Health Information" or "PHI" means any information, whether oral or recorded in any form or medium: (i) that relates to the past, present or future physical or mental condition of an individual, the provision of health care to an individual, or the past, present or future payment for the provision of health care to an individual; and (ii) that identifies the individual or with respect to which there is a reasonable basis to believe the information can be used to identify the individual, and shall have the meaning given to such term under HIPAA and the HIPAA Regulations, including, but not limited to 45 CFR Section 160.103. [45 CFR Parts 160, 162 and 164]

d. "Electronic Protected Health Information" or "ePHI" means any information that is transmitted or maintained in electronic media: (i) that relates to the past, present or future physical or mental condition of an individual, the provision of health care to an individual, or the past, present or future payment for the provision of health care to an individual. and (ii) that identifies the individual or with respect to which there is a reasonable basis to believe the information can be used to identify the individual, and shall have the meaning given to such term under HIPAA and the HIPAA Regulations, including, but not limited to 45 CFR Section 160.103. [45 CFR Parts 160, 162 and 164]

e. "Electronic Media" shall have the meaning given to such term under HIPAA and the HIPAA Regulations, including but not limited to, 45 CFR Section 160.103.

f. "Security incident" shall have the meaning given to such term under HIPAA and the HIPAA Regulations, including but not limited to, 45 CFR Section 164.304.

2. **Obligations of Associate.**

a. Permitted Uses and Disclosures. Associate may use and/or disclose PHI received by Associate pursuant to the Agreement ("County's PHI") solely in accordance with the specifications set forth in the Scope of Services, Appendix A. In the event of any conflict between this Addendum and Appendix A, this Addendum shall control. [45 CFR § 164.504(e)(2)(i)]

b. Nondisclosure. Associate shall not use or further disclose County's PHI other than as permitted or required by law. [45 CFR § 164.504(e)(2)(ii)(A)]

c. Safeguards. Associate shall use appropriate safeguards to prevent use or disclosure of County's PHI in a manner other than as provided in this Addendum. [45 CFR § 164.504(e)(2)(ii)(B)] Associate shall maintain a comprehensive written information security program that includes administrative, technical and physical safeguards appropriate to the size and complexity of the Associate's operations and the nature and scope of its activities. Appropriate safeguards used by Associate shall protect the confidentiality, integrity, and availability of the PHI and ePHI that is created, received, maintained, or transmitted on behalf of the County. [45 CFR § 164.314(a)(2)(i)(A)] County has at its sole discretion, the option to audit and inspect, the Associate's safeguards at any time during the life of the Agreement, upon reasonable notice being given to Associate for production of documents and coordination of inspection(s).

d. Reporting of Disclosures. Associate shall report to the County's Project Manager, any use or disclosure of the County's PHI in a manner other than as provided in this Addendum. [45 CFR § 164.504(e)(2)(ii)(c)] Associate shall report to the County through the County's Project Manager, any security incident of which it becomes aware within forty-eight (48) hours of discovery of the incident. [45 CFR § 164.314(a)(2)(i)(C)]

e. Associate's Agents. Associate agrees and shall ensure that any agents, including subcontractors, to whom it provides PHI received from (or created or received by Associate on behalf of) the County, agrees in writing to the same restrictions and conditions that apply to Associate with respect to such PHI and that such agents conduct their operations within the United States. Associate agrees and shall ensure that any agents, including subcontractors, to whom it provides ePHI received, created, maintained, or transmitted on behalf of the County, agrees in writing to implement reasonable and appropriate safeguards to protect the confidentiality, integrity, and availability of that ePHI. [45 CFR § 164.314(a)(2)(i)(B)] In no case may Associate's Agents reside and operate outside of the United States.

f. Documentation of Disclosures. Associate agrees to document disclosures of the County's PHI and information related to such disclosures as would be required for the County to respond to a request by an individual for an accounting of disclosures of PHI. Associate agrees to provide the County or an individual, in a time and manner designated by the County, information collected in accordance with the Agreement, to permit the County to respond to such a request for an accounting. [45 CFR § 164.528]

g. Availability of Information to County. Associate shall make available to the County such information as the County may require to fulfill the County's obligations to provide access to, provide a copy of, and account for, disclosures of PHI pursuant to HIPAA and the HIPAA Regulations, including, but not limited to, 45 CFR Sections 164.524 and 164.528. [45 CFR § 164.504(e)(2)(ii)(E) and (G)]

h. Amendment of PHI. Associate shall make the County's PHI available to the County as may be required to fulfill the County's obligations to amend PHI pursuant to HIPAA and the HIPAA Regulations, including, but not limited to, 45 CFR Section 164.526 and Associate shall, as directed by the County, incorporate any amendments to the County's PHI into copies of such PHI maintained by Associate, and in the time and manner designated by the County. [45 CFR § 164.504(e)(2)(ii)(F)]

i. Internal Practices. Associate shall make its internal practices, books and records relating to the use and disclosure of the County's PHI (or PHI created or received by Associate on behalf of the County) available to the County

and to the Secretary of the U.S. Department of Health and Human Services in a time and manner designated by the County or the Secretary for purposes of determining Associate's compliance with HIPAA and the HIPAA Regulations. [45 CFR § 164.504(e)(2)(ii)(H) and 45 CFR Part 64, Subpart C.]

j. Mitigation. Associate agrees to mitigate, to the extent practicable, any harmful effect that is known to Associate of a use or disclosure of the County's PHI by Associate in violation of the requirements of this Addendum.

k. Associate's Insurance. Associate agrees to maintain the insurance coverage provided in the Agreement.

l. Notification of Breach. Associate shall notify the County within twenty-four (24) hours, and shall provide written notice no later than forty-eight (48) hours of any suspected or actual breach of security, intrusion or unauthorized disclosure of PHI and/or any actual or suspected disclosure of data in violation of any applicable federal or state laws or regulations. Associate shall take (i) prompt corrective action to cure any such deficiencies, and (ii) any action pertaining to such unauthorized disclosure required by applicable federal and state laws and regulations.

m. Expenses. Any and all expenses incurred by Associate in compliance with the terms of this Addendum or in compliance with the HIPAA Regulations shall be borne by Associate.

n. No Third Party Beneficiary. The provisions and covenants set forth in this Agreement are expressly entered into only by and between Associate and the County and are intended only for their benefit. Neither Associate nor the County intends to create or establish any third party beneficiary status or right (or the equivalent thereof) in any other third party nor shall any other third party have any right to enforce or enjoy any benefit created or established by the provisions and covenants in this Agreement.

3. Audits, Inspection and Enforcement. From time to time, after reasonable notice, upon any breach of this Addendum by Associate, the County may inspect the facilities, systems, books and records of Associate to monitor compliance with this Addendum. Associate shall promptly remedy any violation of this Addendum and shall certify the same to the County in writing. The fact that the County inspects, or fails to utilize its right to inspect, Associate's facilities, systems, books, records, and procedures does not relieve Associate of its responsibility to comply with this Addendum, nor does the County's (i) failure to detect or (ii) detection, but failure to notify Associate or require Associate to remedy such breach, constitute acceptance of such practice or a waiver of the County's enforcement rights under this Addendum.

4. Termination.

a. Material Breach. A breach by Associate of any provision of this Addendum, shall constitute a material breach of the Agreement and shall provide grounds for immediate termination of the Agreement by the County. [45 CFR § 164.504(e)(3) and 45 CFR § 164.314(a)(2)(i)(D)]

b. Termination for Cause - Reasonable Steps to Cure Breach. If the County recognizes a pattern of activity or practice of Associate that constitutes a material breach or violation of the Associate's obligations under the provisions of this Addendum and does not terminate the Agreement pursuant to Section 4a, above, the County may provide an opportunity for Associate to end the violation or cure the breach within five (5) days, or other cure period as may be specified in the Agreement. If Associate does not cure the breach or end the violation within the time period provided, the County may immediately terminate the Agreement.

c. Judicial or Administrative Proceedings. The County may terminate the Agreement, effective immediately, if (i) Associate is named as a defendant in a criminal or administrative proceeding for a violation of HIPAA, or (ii) a finding or stipulation that Associate has violated any standard or requirement of the HIPAA Regulations (or other security or privacy law) is made in any administrative or civil proceeding.

d. Effect of Termination. Upon termination of the Agreement for any reason, Associate shall return or destroy as directed by the County all PHI, including but not limited to ePHI, received from the County (or created or

received by Associate on behalf of the County) that Associate still maintains in any form. This provision shall also apply to County PHI that is in the possession of subcontractors or agents of Associate. Associate shall retain no copies of such PHI or, if return or destruction is not feasible, Associate shall provide to the County notification of the conditions that make return or destruction infeasible, and shall continue to extend the protections of this Addendum to such information, and limit further use or disclosure of such PHI to those purposes that make the return or destruction of such PHI infeasible. [45 CFR § 164.504(e)(2)(ii)(I)]

5. **Indemnification.** Associate shall indemnify and hold harmless the County and its officers, employees, trustees, agents, and instrumentalities (the indemnified parties) from any and all liability, losses or damages, including attorneys' fees and costs of defense, which the County or its officers, trustees, employees, agents or instrumentalities may incur as a result of claims, demands, suits, causes of actions or proceedings of any kind or nature arising out of, relating to, or resulting from the performance of this Addendum by Associate or its employees, agents, servants, partners, principals, or subcontractors. Associate shall pay all claims and losses in connection therewith and shall investigate and defend all claims, suits, or actions of any kind or nature in the name of any of the indemnified parties, where applicable, including appellate proceedings, and shall pay all costs, judgments, and attorney's fees which may issue thereon. Associate expressly understands and agrees that any insurance protection required by this Addendum, or otherwise provided by Associate, shall in no way limit the responsibility to indemnify, keep and save harmless and defend the indemnified parties as herein provided. This paragraph shall survive the termination of the Agreement.

6. **Limitation of Liability.** Nothing in this Addendum shall be construed to affect or limit the County's sovereign immunity as set forth in Florida Statutes, Section 768.28.

7. **Amendment.**

a. Amendment to Comply with Law. The parties acknowledge that state and federal laws relating to the security and privacy of PHI, including electronic data, are rapidly evolving and that amendment of this Addendum may be required to provide for procedures to ensure compliance with such developments. The parties specifically agree to take such action as is necessary to implement the standards and requirements of HIPAA, the HIPAA Regulations and other applicable laws relating to the security or confidentiality of PHI. The parties understand and agree that the County must receive satisfactory written assurance from Associate that Associate will adequately safeguard all PHI that it receives or creates pursuant to this Agreement. Upon the County's request, Associate agrees to promptly enter into an amendment to the Agreement embodying written assurances consistent with the standards and requirements of HIPAA, the HIPAA Regulations or other applicable laws. The County, in addition to any other remedies including specific performance, may terminate the Agreement upon five [5] days' written notice in the event Associate does not enter into said amendment to the Agreement providing assurances regarding the safeguarding of PHI that the County, in its sole discretion, deems sufficient to satisfy the standards and requirements of HIPAA and the HIPAA Regulations. Notwithstanding Associate's failure to enter into an amendment, Associate shall comply with all provisions of the HIPAA laws.

8. **Assistance in Litigation or Administrative Proceedings.** Associate shall make itself, and any subcontractors, employees or agents assisting Associate in the performance of its obligations under this Agreement, available to the County at the County's convenience upon reasonable notice, at no cost to the County, to testify as witnesses, for document production, or otherwise, in the event of litigation or administrative proceedings being commenced against the County, its trustees, officers, agents or employees based upon claimed violation of HIPAA, the HIPAA Regulations or other laws relating to security and privacy, except where Associate or its subcontractor, employee or agent is a named adverse party.

9. **Effect on Agreement.** Except as specifically required to implement the purposes of this Addendum, or to the extent inconsistent with this Addendum, all other terms of the Agreement shall remain in force and effect. In the event of any conflict between this Addendum and Agreement, this Addendum shall control.

10. **Interpretation.** This Addendum and the Agreement shall be interpreted as broadly as necessary to implement and comply with HIPAA, the HIPAA Regulations and applicable Florida laws. The parties agree that any ambiguity in

this Addendum shall be resolved in favor of a meaning that complies and is consistent with HIPAA and the HIPAA Regulations.

11. **Jurisdiction**. Any litigation between the parties regarding the terms of this Addendum shall take place in Miami-Dade County, Florida.

APPENDIX D

Testing Procedure Protocols A through F3- Employee Testing & Medical Assessment Services

Attachments:

- A Standard Pre-employment Examination for Selected Applicants
- A1 Modified Pre-employment Examination for Selected Applicants
- B High Stress Physical Examination
- C Miami-Dade County Scientific and Administrative Protocol for the Alcohol and Drug Abuse Workplace Policy
- D Fitness for Duty Physical Examination
- E Medical Surveillance Program and Exposure Testing Required by OSHA
- F Department of Transportation Drug and Alcohol Testing Programs
- F1 Procedures for Transportation Workplace Drug and Alcohol Testing Programs (Part 40)
- F2 Prevention of Alcohol Misuse and Prohibited Drug Use in Transit Operations (Part 655)
- F3 Controlled Substances and Alcohol Use and Testing (Part 382)

ATTACHMENT A

PROTOCOL

Miami-Dade County Employee's Medical Assessment and Testing Procedures

Standard Pre-employment Examination for Selected Applicants

I. MEDICAL HISTORY SHEET:

Applicant will complete a family and personal medical history to be reviewed by the physician with him/her at the time of the physical examination.

II. LABORATORY WORK-UP:

A. URINALYSIS:

Albumin	Urobilinogen
Protein	Bilirubin
PH	Nitrite
Blood	Specific Gravity
Ketone Bodies	Microscopic

B. TB TINE TEST/CHEST X-RAY:

Perform a TB Tine Test on each applicant. If results are positive, then do a Chest X-Ray (Standard size posterior - anterior view). Chest X-Ray must be interpreted by a radiologist.

III. EYE TEST:

Testing should be standard binocular screening device. The test should screen for both near and far distance acuity on an instrument that checks for keenness of vision, depth perception, balance of eye muscles, and the ability to differentiate between colors.

IV. HEARING CHECK:

Any method such as tuning fork or whisper to evaluate frequencies in conversational range.

V. PULMONARY FUNCTION TEST (Vital Lung Capacity):

A spirometer test which measures on a graph at what capacity an individual can expel a volume of air following full inspiration; will be performed on anyone whose job exposes him/her to environmental irritants. This test should be performed on a spirometer that measures functions by volume, not flow.

SD

VI. URINE DRUG AND ALCOHOL TESTING:

Urine drug and alcohol screening shall be performed on each applicant in accordance with the Miami Dade County Scientific and Administrative Protocol for the Alcohol and Drug Abuse Workplace Policy (See Attachment C).

VII. PHYSICAL EXAMINATION BY:

Palpation Observation
Auscultation Percussion

To include the following:

Vital signs - TPR, Blood Pressure (both arms)
Height
Weight
Head, scalp, face
Neck (thyroid, lymphs, vessels)
Eyes (fundi, focus), general
Ocular motility
Pupils (equality and reaction)
Ears (int. & ext. canals-cerumen)
Ear drums (perforation)
Nose (sinuses)
Mouth (tongue, teeth, gums)
Throat (condition of tonsils)
Lungs, chest (include breast)
Heart (thrust, size, rhythm, sounds)
Vascular System (varicosities, etc.)
Abdomen, Viscera (check hernias)
Anal and rectal digital exam
Endocrine System
External Genitalia
Pelvic examination
Upper extremities (strength, range of motion)
Lower extremities (strength, range of motion)
Spine, other musculoskeletal
Skin (scars/rash) lymphatics
Neurological
Mental Stability/Health
Equilibrium
General Appearance

The Standard Physical Examinations will be executed by the physician, using his medical judgment as it relates to the occupation of the applicant or employee. An Essential Job Function Form can be request from the County to get a description of duties required of the occupation.

ATTACHMENT A-1

PROTOCOL

Miami-Dade County Employee's Medical Assessment and Testing Procedures

Modified Pre-employment Examination for Selected Applicants

I. MEDICAL HISTORY SHEET:

Applicant will complete a family and personal medical history to be reviewed by a physician to identify medical abnormalities.

II. LABORATORY WORK-UP:

A. URINALYSIS:

Albumin	Urobilinogen
Protein	Bilirubin
PH	Nitrite
Blood	Specific Gravity
Ketone Bodies	Microscopic

III. URINE DRUG AND ALCOHOL TESTING:

Urine drug and alcohol screening shall be performed on each applicant in accordance with the Miami Dade County Scientific and Administrative Protocol for the Alcohol and Drug Abuse Workplace Policy (See Attachment C).

The Modified Physical Examinations will be reviewed by a physician, using his medical judgment as it relates to the occupation of the applicant or employee. Any significant abnormalities found in the applicants medical history or urinalysis will require the employee to complete a full Standard Pre-employment Examination. An Essential Job Function Form can be request from the County to get a description of duties required of the occupation.

ATTACHMENT B

PROTOCOL

Miami-Dade County Employee's Medical Assessment and Testing Procedures

High Stress Physical Examination

PHASE 1

I. MEDICAL HISTORY SHEET:

Examinee will complete a family and personal medical history to be reviewed by the physician with him/her at time of physical exam. The medical history sheet should include the following:

A. Past medical history
B. Past surgical history
C. Past immunizations
D. Family History
E. Occupational History
F. Habits
G. Exercise Habits
H. Review of Systems

II. LABORATORY WORK-UP:

A. HEMATOLOGY PANEL (CBC):

Red blood cell count	Mean Corpuscular Volume
White blood cell count	Mean Corpuscular Hemoglobin
Hemoglobin	Mean Corpuscular Hemoglobin Concentration
Hematocrit	Differential

B. BLOOD CHEMISTRY (SMAC-26):

Glucose	Sodium
Urea Nitrogen	Potassium
Uric Acid	Chloride
Cholesterol	CO^2
Total Protein	Creatinine
Alkaline Phosphatase	Triglycerides
Lactic Dehydrogenase	(LDH) Iron
Transaminase (SGOT)	A/G Ratio
GGTP SGPT	Globulin
Calcium	Indirect Bilirubin
Phosphorus	Direct Bilirubin
Total Bilirubin	Bun/Creatinine Ratio

Albumin	Total Cholesterol
	HDL Cholesterol
	LDL Cholesterol
	HDL/Total Cholesterol Ratio

C. URINALYSIS:

Albumin	Urobilinogen
Protein	Bilirubin
PH	Nitrite
Blood	Specific Gravity
Ketone Bodies	Microscopic

D. PAP SMEAR - Optional (Females)

E. SICKLE CELL ANEMIA TEST

Not for pre-employment physicals.

III. EYE TEST:

Testing should be standard binocular screening device. The test should screen for both near and far distance acuity on a scientifically accurate instrument that checks for keenness of vision, depth perception, balance of eye muscles, and the ability to differentiate between colors.

* Vision acuity for Firefighters must be without corrective lenses.

Tonometry test for glaucoma, for those over 40 years of age.

IV. HEARING CHECK:

Audiometric testing must be at the frequencies of 500, 1000, 2000, 3000, 4000, 6000 and 8000 Hertz. It shall be accomplished with a certified, currently calibrated audiometer with testing in an environment meeting current ANSI standards, and testing accomplished by a certified Audiometric technician (CADHC) or a certified Clinical Audiologist (CCC) or a Medical Doctor.

Audiogram must include for legal purposes:

1. Identifications of employee (name, social security number, employee number, department)
2. Date and time of testing
3. Employee thresholds at frequencies described above
4. History including prior noise exposure
5. Standards and date of audiometric calibration
6. Signature of tester
7. Signature of employee

V. PULMONARY FUNCTION TEST (VITAL LUNG CAPACITY):

A spirometer test which measures, on a graph, at what capacity an individual can expel a volume of air following full inspiration. This test should be performed on a spirometer that measures functions by volume, not flow. The minimal reported information should be FEV, FVC, FEV/FVC ratio, MMEF and MVV. All volumes should be reported in absolute values (liters) as well as percentage of age and sex-adjusted norms.

VI. RADIOLOGY STUDY:

A. CHEST RADIOGRAPH (STANDARD POSTERIOR-ANTERIOR AND LATERAL):

All applicants shall be given a Chest X-Ray.

Non-smokers without significant environmental exposures should have no more than one (1) chest x-ray every three (3) years and should be discouraged from routine chest radiographs. The x-ray must be interpreted by a radiologist.

B. MAMMOGRAM:

All women of age 35 (or older if they have not been tested) should be given Baseline Mammogram. Then Mammograms will be given periodically at age 40 and every two (2) years thereafter. The Mammogram must be interpreted by a radiologist.

C. BODY SCANNING

Specific employees will be eligible to receive a "full or partial body scan" with approval from the County. The body area included extends only from the shoulders to the top of the thighs. The Body Scan must be interpreted by a radiologist.

VII. SKIN TEST:

Indradermal Test for Tuberculosis exposure should be done on all employees dealing with public (especially rescue work, fire, police and lifeguards). Do not repeat if the patient is a known Positive Reacter, but note the reactivity in the record.

VIII. TETANUS TOXOID BOOSTER:

Immunization to be given if not received anytime within the past ten (10) years. D-T Toxoid may be used instead of Tetanus Toxoid.

IX. ELECTROCARDIOGRAM:

12 lead EKG is done in resting state. Shall be interpreted by a cardiologist certified by the American Board of Internal Medicine with a subspecialty in cardiovascular disease. The report with mounted rhythm strip shall be included in medical chart.

X. ANTHROPOMORPHIC MEASUREMENTS:

a. Blood Pressure
b. Heart Rate
c. Height
d. Weight
e. Temperature
f. Skinfold measurements (for evaluation of obesity)

PHASE II

I. PHYSICAL EXAMINATION:

A. Head and Neck

1. Eyes: Examination of eye movements, pupils, sclera and Ophthalmoscopic examination of fundus.
2. Ears: Examination of external ears; Otoscopic examination of ear canal and ear drum.
3. Nose: Otoscopic examination of interior of nose to include nares.
4. Mouth: Visual examination of tongue, teeth, floor and roof of mouth, manual palpation of any abnormal masses.
5. Neck: Palpation of thyroid, trachea, lymph nodes and neck for masses or nodules.

B. Breast

Visual inspection and palpation of breasts and nipples. During this examination also instruct in the self-examination of breasts.

C. Chest and Lungs

Inspection and contour of chest; auscultation of lungs with stethoscope.

D. Spine and Back

Visual inspection for deformity and cervical and Lumbar-Sacral range of motion palpation of vertebral bodies, par spinal muscles and kidneys.

E. Cardiovascular

1. Heart: Palpation of chest wall for heartbeat and abnormalities; auscultation of heart with stethoscope for abnormal sound and murmurs.

2. Arteries: Palpation of pulses in neck, arms and legs; auscultation of neck for carotid bruits.

F. Abdomen

Visual inspection of abdominal wall; palpation of abdomen for masses and abdominal organs, auscultation of abdomen for bowel sounds and bruits, and examination of hernias.

G. Rectal

Routine in men over 35 and women over 40, and also when indicated. Palpation of prostate for nodules, size and abnormalities, palpation of rectal vault for tumors and abnormalities and stool for occult blood (screening test for colon cancer).

H. Extremities

Visual examination for varicose veins or other abnormalities, palpation and evaluation of edema, and a directed exam of any abnormalities of the muscles strength or joints.

I. Skin

Visual examination of skin (due to amount of skin on body; patient direction of abnormalities should be encouraged).

J. Neurological Examination

Examination of cranial nerves for abnormality of head and neck motion, examination of reflexes, examination of sensation and examination of balance, strength and cognitive ability, when appropriate.

K. Male Genitalia

Visual examination of penis and testicular sac and manual palpation of testicles and epididymis.

II. TREADMILL STRESS TEST

A treadmill stress test shall be offered to executives completing an executive physical unless not recommended by the examining physician.

A. Routine Stress Testing is not recommended for all patients.

B. Stress Test recommended for the following indications:

1. Prior to institution of vigorous exercise programs in those over 35 years of age.

2. If two or more risk factors below for coronary artery disease and if age is over 35:

Hypertension
Diabetes mellitus
Hyperlipoproteinemia
Obesity
Smoking history
Positive family history

C. For evaluation of chest pain of unknown etiology

D. Evaluation of abnormal EKG's

E. Evaluation of known coronary artery disease

The stress test must be administered by a qualified cardiologist, preferably with experience in exercise physiology.

The High Stress Physical Examination will be initiated to employees and applicants identified by the County who perform high risk duties, the County will provide the specific medical and physical standards for employees and applicants that fit these categories:

Firefighter
Police Officer
Correction Officer
Bus Operator

All other High Stress Physical Examinations will be executed by the physician, using his medical judgment as it relates to the occupation of the applicant or employee. An Essential Job Function Form can be requested from the County to get a description of duties required of the occupation.

ADDITIONAL SERVICES AS REQUIRED:

A. Blood Alcohol Test: The collection of blood in accordance with the Drug Testing Protocol (Attachment C) in the event of a positive result on the breath alcohol screening, a reasonable suspicion test or when specified by the Human Resources Department.

B. Drug/Alcohol Confirmation Test (GS/MS): Confirmation Test (GS/MS) to be performed in accordance with the Drug Testing Protocol (Attachment C) in the event of a positive initial screening result for drugs or alcohol.

C. AUDIOGRAM:

Audiometric testing must be at the frequencies of 500, 1000, 2000, 3000, 4000, 6000 and 8000 Hertz. It shall be accomplished with a certified, currently calibrated audiometer with testing in an environment meeting current ANSI standards, and testing accomplished by a certified Audiometric technician (CADHC) or a certified Clinical Audiologist (CCC) or a Medical Doctor.

D. VISION TESTING & AUDIOGRAM

E. TB TEST

F. LEAD LEVEL BLOOD TESTS

G. CHEST X-RAY, PPD TEST, HEPATITIS SCREEN

H. PPD TEST, HEPATITIS SCREEN

I. AUDIOMETRIC TESTING/EVALUATION:

These are annual audiograms required by OSHA guidelines for certain employee classifications. This includes the evaluation by a physician of prior audiograms to determine potential hearing loss.

J. FITNESS FOR DUTY PHYSICAL (INDEPENDENT MEDICAL EVALUATION):

This includes consultation with employee's private physician, review of employee's medical records, examination of employee and narrative report for employer.

K. MEDICAL REVIEW OFFICER - CHARGE PER HOUR:

L. SPECIAL EYE EXAMINATION:

Bidding on this test is optional.

Exam to be performed by a trained Ophthalmic Technologist. Exam must include visual acuity and correction, anterior segment examination including intraocular pressure check and dilated eye exam for fundus exam of retina. Test is for fingerprint technicians and photographers using copper vapor laser.

M. MEDICAL SURVEILLANCE PROGRAM AND EXPOSER TESTING REQUIRED BY OSHA:

This requires all employees exposed or potentially exposed to hazardous substances or health hazards above permissible exposure limits for more than 30 days per year be evaluated by a physician.

N. HAZMAT TESTING

O. HEAVY METALS TESTING

P. CHOLENESTEREASE TESTING

Q. LEAD AND ZINC PROTOPORPHYRIN TESTING

R. PSA TEST

Prostate Specific Antigen for all Firefighters, and men meeting the following profile: age 50 and over or with a history of prostate problems. This blood test will be performed only at annual exam, not for pre-employment physicals.

ATTACHMENT C

P R O T O C O L

Miami-Dade County Employee's Medical Assessment and Testing Procedures

MIAMI-DADE COUNTY

SCIENTIFIC AND ADMINISTRATIVE PROTOCOL

FOR THE

ALCOHOL AND DRUG ABUSE WORKPLACE POLICY

APRIL 1, 1992

SCIENTIFIC AND TECHNICAL REQUIREMENTS

THE DRUGS

Miami-Dade County has established a policy regarding alcohol and drug abuse testing of existing employees and the final selectees in all County positions.

Potentially, drug testing could be accomplished to detect hundreds of substances classified in schedule I and II of the Controlled Substances Act. Legal use of any of these "drugs" requires a legal prescription or an exemption authorized by appropriate laws.

It is not practical to test for all of them, therefore, the following guidelines have been developed that are consistent with standards developed for use by Federal civilian and Department of Defense drug testing programs.

Miami-Dade County drug testing programs shall test for alcohol and drugs as indicated below:

Test 1: Police Officers, Correctional Officers, and applicants for those positions shall be tested for:

Alcohol
Amphetamines
Barbiturates
Benzodiazepines
Cocaine
Opiates
Marijuana
Methaqualone
Phencyclidine (PCP)

Test 2: Firefighters, Bus Operators, Rail Attendants and employees in other Safety Sensitive Positions (as determined by the Office of Labor Management and the Employee Relations Department) and applicants for those positions shall be tested for:

Alcohol
Barbiturates
Benzodiazepines
Cocaine
Opiates
Marijuana
Phencyclidine (PCP)

Test 3: All other applicants and employees shall be tested for:

Alcohol
Cocaine
Marijuana

Test 4: Police Officers, Correctional Officers, Firefighters, and Lifeguards - During certain physical examinations as indicated below for these positions, a second urine sample shall be collected in order that the presence of anabolic steroids and their metabolites may be detected:

1. Pre-employment physicals, as determined by the examining physician in conjunction with the list of Indicators of Possible Anabolic Steroid Use.
2. Annual physicals, as determined by the examining physician in conjunction with the list of Indicators of Possible Anabolic Steroid Use.
3. Fitness for Duty physicals, if physical is requested due to a performance related problem and the physician concludes that the problem may be related to steroid use.
4. Reasonable Suspicion tests, at the requesting department's discretion.

The Indicators of Possible Anabolic Steroid Use to be used by examining physicians during the pre-employment and annual physical examinations listed above are as follows:

Physical Characteristics

Men

1. Skeletal muscle hypertrophy
2. Testicular atrophy
3. Gynecomastia
4. Acne

Women

1. Skeletal muscle hypertrophy
2. Virilism (clitoral hypertrophy, hirsutism)
3. Alopecia (balding)
4. Acne

Blood Chemistry Characteristics- for both men and women

1. Hyperglycemia
2. Increased Triglycerides
3. Decreased HDL to LDL cholesterol ratio, with increased total LDL and decreased total HDL cholesterol.

If any of the indicators in the profile is present, the examining physician may authorize the collection of an additional urine sample for testing for the presence of anabolic steroids and their metabolites.

TARGETED ANABOLIC STEROID PROFILE

The Miami-Dade County anabolic drug testing program shall test for the presence of the following anabolic steroids and their metabolites:

Boldenone
Methandienone (Dianabol)
Methyltestosterone
Nandrolone (19-Nortestosterone)
Stanozolol

Epitestosterone
Testosterone

Testosterone/Epitestosterone Ratio
Oxandrolone (Anavar)
Oxymetholone (Anadrol)
and related drugs of abuse as designated by the County and its contractors.

THE CONTRACT FACILITIES

Each Physical Exam Provider shall contract with a laboratory (or laboratories) which meet(s) all the requirements set forth in this document. The Provider shall submit to the County for approval, a statement from the laboratory as to:

1. Its ability to comply with each requirement in this Scientific and Administrative Protocol.
2. Whether such laboratory is currently licensed in accordance with the "Laboratory Facilities" section on page 33 and copies of any relevant licensing documents.
3. The names and qualifications of each laboratory staff member in accordance with the "Laboratory Personnel" section on page 33, including a resume for those employees likely to testify in accordance with the "Judicial Proceedings" section on page 38, and copies of any relevant documents setting forth such qualifications.
4. The use of a quality control program, including a copy of any such program or any laboratory procedures which include such a program.
5. The planned method of transportation of specimens from the collection site to the laboratory.
6. Any other information the laboratory determines to be relevant to the approval process.

SPECIMEN COLLECTION PROCEDURES

COLLECTION SITE

The collection site is defined as a place where individuals present themselves for the purpose of providing breath, blood, urine, or saliva specimens to be analyzed for alcohol and drugs of abuse. The site must possess all necessary personnel, materials, equipment, facilities, and supervision to provide for the collection, security, temporary storage, and transportation (shipping) of blood and urine specimens to a drug testing laboratory.

The collection site facility shall be secure at all times. In cases where the facility cannot be dedicated solely for the purpose of alcohol and drug testing, it shall be secured as a collection site facility during drug testing operations. Chain of custody forms must be properly executed by authorized collection site personnel upon receipt of specimens. (See Attachment I, Chain of Custody (COC) form). The handling and transportation of all specimens from one authorized individual or place to another must always be accomplished through the use of chain of custody procedures. No unauthorized personnel shall be permitted in any part of the collection site where specimens are collected or stored.

SPECIMEN COLLECTION

Procedures for providing urine specimens must allow individual privacy while providing for reasonable precaution to ensure that a urine specimen has not been adulterated or diluted during the collection

procedure and that all information on the urine bottle and in the log book can be identified as belonging to a given individual. To ensure that unadulterated specimens are obtained, the following procedures outline the minimum precautions that shall be taken during the collection of urine specimens:

NOTE: If urine specimens for both Tests 1, 2,or 3 and Test 4 are to be collected at the same time, all of the following steps should be performed. If a urine specimen for Test 4 is to be collected during a separate visit, then where steps are marked "a" and "b", only those steps marked "b" should be performed, and steps 3 and 15 should be eliminated.

1. Upon arrival of the individual at the collection site, the collection site agent shall request the individual to present some type of photo identification, i.e., County I.D., driver's license, or identification preferably with both photo and social security number. If the individual does not have proper identification, this shall be noted on the chain of custody form.
2. The collection site agent shall request the individual to remove all clothing and to put on a gown (paper or cloth) provided by the collection site agent. The individual shall leave all clothing and personal belongings in the examining room with the door closed. The collection site agent verifies that all clothing has been removed and notes any unusual behavior or appearance of individuals attempting to circumvent these procedures.
3. The collection site agent will administer the breath alcohol screening test by requesting the individual to blow into the approved screening device. The collection site agent will show the reading on the breath alcohol screening instrument to the individual prior to entering the result on the chain of custody form. The individual will verify that the proper reading is entered on the form. If the reading is .04% or above, blood will be drawn for a confirmation test.
4. The collection site agent will place identification labels on the appropriate specimen containers in the following manner:

4a. The collection site agent will place identification labels on two specimen containers for Test 1 through 3 and, if urine alcohol test is needed, a third container must be labeled. The identification labels should contain the name and social security number of the individual. The individual shall verify that the information contained on all labels is correct.
NOTE: Special specimen containers which are sterile must be used for codes AO, PO and 45O defined in item 5 below.

4b. When indicated by the criteria for Test 4, the collection site agent will place an identification label on a container designated for testing for anabolic steroids. The label should contain the name and social security number of the individual. The individual shall verify that the information contained on the label is correct

5. The collection site agent will prepare the toxicology submission forms, copies of which will be kept in a notebook as a log. (Two forms are needed if specimens for both Test 1, 2, or 3 and Test 4 are collected at the same time.) Copies of both forms will be kept in a notebook as a log. Each form must contain the time, date, collection site, individual's name and social security number, specimen number, code from the list below indicating the purpose of the test, and any other information required by the County.

A = Annual for all employees except executives, police and correctional officers, firefighters and specified safety sensitive positions

P = Pre-employment except executives, police and correctional officers, firefighters and safety sensitive positions

AO = Annual for police officers and correctional officers
AF = Annual for firefighters
PF = Pre-employment for firefighters
RS = Reasonable Suspicion
RTA = Random Test per Agreement
FIT = Fitness for Duty
45 = 45 Day Rule (Drug and alcohol test only)
45O = 45 Day Rule for police officers and correctional officers (drug and alcohol test only)
45S = 45 Day Rule for safety sensitive positions (drug and alcohol test only)
EA = Executive Annual
EP = Executive Pre-employment
SA = Safety Sensitive Annual, including Bus Operators and Rail Attendants (but excluding Police and Correctional Officers and Firefighters)
SP = Safety Sensitive Pre-employment, including Bus Operators and Rail Attendants (but excluding Police and Correctional Officers and Firefighters)
PRO = Promotional Standard Physical

The individual shall verify that all information contained on the form is correct.

6. At the collection site, toilet bluing agents shall be placed in the toilet tank.
7. The individual shall be instructed to enter the restroom and, while leaving the door open, rinse and dry hands prior to urination. The individual shall be given a wrapped clear plastic container for the collection of all urine to be tested.
8. The individual shall then close the restroom door and the collection site agent shall remain outside the restroom. The individual shall only be permitted access to cold water from the faucet in the restroom. In the case of testing for reasonable suspicion, either the collection site agent or the County representative should accompany the individual into the restroom and observe the flow of urine into the specimen container.
9. The individual may provide his/her specimen in the privacy of the restroom except as noted for reasonable suspicion cases. The collection site agent shall note any unusual behavior, delays, or lack of cooperation by the individual. The individual providing the specimen should not let the specimen container out of his sight until the container is properly sealed.
10. Upon receiving the specimen(s) from the individual, the collection site agent will verify collection of approximately 60 milliliters of urine for Tests 1 through 3, at least 30 milliliters for Test 4 if required, plus additional required for routine urinalysis. In the event that an approved breath alcohol screening device is not available, alcohol testing will be done through the urine. If there is not sufficient urine in the container, additional urine should be collected. The individual may be given a reasonable amount of water (i.e. a glass). If an individual fails, for any reason, to provide the necessary specimen, or if the individual fails to appear at the collection site at the assigned time, collection site personnel shall contact the County's Employee Relations Department to obtain guidance on action to be taken. The individual shall not be authorized to leave the collection area until an adequate specimen is obtained, or permission is granted by the County Personnel Department or the County Department requesting testing.
11. Immediately after collection, collection site personnel shall conduct, in the presence of the individual, a close inspection of the specimen in its container to determine the specimen's warmth, color, and signs of contaminants. Any unusual findings resulting from the inspection must be included on the chain of custody form. The temperature should be tested immediately by examining the urine specimen collected for routine

66

urinalysis. The specimen should be collected in a container supplied with a built in "strip-type" thermometer. In no event should any object be placed inside the specimen container risking contamination of the specimen. If the temperature is more than + or - .4 degrees from 98.6 degrees Fahrenheit, this gives rise to reasonable suspicion of adulteration or substitution. Another specimen should be collected under direct observation and both specimens forwarded to the laboratory with the appropriate notes made by the collector.

12. The specimen shall then be split by the collection site agent to accommodate the number of tests to be completed.

12a. For Test 1, 2, and 3 the specimen shall be split by pouring into two containers for use in non-steroid drug testing, and a third for alcohol if required, which have been labeled in accordance with step 4a on page 9 of this protocol. The collection site agent shall request the individual to observe the transfer of the specimen to the two labeled containers. The individual shall observe the capping of all containers. The collection site agent will then enter on the submission form the time at which the specimen was collected.

12b. For Test 4 the specimen shall be poured into the container for use in steroid testing, which has been labeled in accordance with step 4b on page 9 of this protocol. The collection site agent shall request the individual to observe the transfer of the specimen to the labeled container. The individual shall observe the capping of the container. The collection site agent will then enter on the submission form the time at which the specimen was collected.

13. The individual shall sign the labels on all specimen bottles. Then the collection site agent will, in the individual's presence, seal all the containers with approved tamperproof security tape placed over the bottle caps and down the sides of the bottles, and, in the case of Test 4, sealed in bag and box. The individual must initial all tapes and the sealed boxes.

14. Both the collection site agent and the individual shall sign the toxicology submission form(s) where indicated. The collection site shall keep copies of all submission forms in numerical order in a notebook. Submission forms must contain all information contained on the identification label, as specified in steps 4a and 4b on page 9 of this protocol.

15. Blood alcohol screening: Such screening shall be done only for reasonable suspicion tests, or when a positive alcohol result is indicated on the alcosensor or other approved breath alcohol screening device, or when requested by the County. Two blood specimens shall be collected in grey top vacutainers for shipment to the laboratory for testing. Cleanse arm with a nonalcoholic swab, etc. Identification, labeling, toxicology submission form entries and signature requirements will be the same as for the urine specimens, except that blood will be collected into two containers and will not be poured off.

16. The individual shall be asked to read and sign a certification statement regarding his/her urine and/or blood specimens. This statement will include a medication history of currently used prescription and over the counter drugs taken by the individual in the past two (2) weeks. A copy of this statement will accompany the specimens to the laboratory, or will be transmitted via electronic means at the request of the testing laboratory.

17. The collection site agent must complete an appropriate chain of custody form.

NOTE: While performing any part of the chain of custody procedures, it is essential that the specimens and custody documents be under the control of the collection site agent. The collection site agent must not leave the site collection area until the specimens are properly secured.

Collection site personnel shall always have the container or specimen bottle within custody before and after the individual has turned over the sample to the agent. All containers shall be tightly capped, properly sealed, and labeled. A chain of custody form approved by Miami Dade County shall be utilized for maintaining control and accountability from point of collection to final disposition of specimens. With each transfer of possession, the chain of custody form shall be dated, signed by the individual releasing the specimen, signed by the individual accepting the specimen, and reflect the purpose for transferring possession noted. Every effort should be made to minimize the number of persons handling specimens. In no event shall the specimens be removed from the sight of the employee/applicant until the containers are capped and sealed in their presence and the labels are signed by the employee/applicant.

INSPECTIONS

The County shall reserve the right to inspect the collection site at any time. The contract with the Physical
Exam Provider shall permit unannounced inspection.

TRANSPORTATION TO LABORATORY

After collection of the appropriate specimens, the collection site personnel shall arrange to ship the specimens to the drug testing laboratory in an expeditious manner, including the certification statement if necessary. A cold chain of control will be initiated to insure that specimens do not remain unrefrigerated for more than 96 hours from time of collection to the time that confirmation tests are completed in the drug testing laboratory. The specimens shall be placed in appropriate containers (specimen boxes or padded mailers) that are securely sealed to eliminate the possibility of tampering. Collection site personnel shall sign and date the tape sealing the container(s) and ensure that the chain of custody documentation is attached to each sealed container. Specimens must be delivered to the drug testing laboratory within 96 hours from time of collection using either the United States Postal Service, commercial air freight, air express, or may be hand carried by bonded courier, authorized laboratory staff or authorized collection site personnel. It is not necessary to send specimens by registered mail. Use of a bonded courier or authorized laboratory or collection site staff to a local laboratory is preferred. When an approved courier service picks up specimens from the collection site for delivery to the laboratory, the chain of custody forms must be signed by delivery personnel and laboratory receiving personnel. In the cases of reasonable suspicion and random testing, specimens for Tests 1 through 3 must be delivered to the drug testing laboratory within 4 hours from time of collection using a bonded courier designated by the collection site and approved by the County. In the case of reasonable suspicion and random testing where Test 4 is required, specimens must be picked up by a bonded courier no later than the following morning for delivery to the drug testing laboratory.

LABORATORY ANALYSIS PROCEDURES

DEFINITIONS

AUTHORIZED PERSONNEL: Individuals determined by the laboratory director to have a need for access to areas used for the receiving, testing, and storage of blood and urine specimens; further, this definition shall include laboratory supervisors with the authority to sign for and take control of blood/urine specimens through the use of the chain of custody format.

CHAIN OF CUSTODY: Refers to the methodology of tracking specified materials and/or substances for the purpose of maintaining control and accountability from initial collection to final disposition for all such materials and/or substances and must provide for accountability at each stage in handling, testing, storing specimens, and reporting test results.

INITIAL DRUG TEST - OTHER THAN ANABOLIC STEROIDS (URINE): A sensitive, rapid, and reliable immunoassay procedure to identify negative and presumptive positive specimens. Some specimens may be subjected to initial testing by methods other than immunoassays, where the latter are unavailable for the detection of specific drugs of special concern. These methods are thin layer, high pressure liquid, and/or gas chromatography. Alternate initial test methods and testing levels shall be submitted for approval to the County.

CONFIRMATORY DRUG TEST - OTHER THAN ANABOLIC STEROIDS (URINE): A second analytical procedure used to identify the presence of a specific drug or metabolite in a urine specimen. The confirmatory test must be different in scientific principle from that of the initial test procedure, although in the case of anabolic steroids the complexity of testing for the drugs requires that GC/MS be used for both the initial screen and the confirmatory test. This confirmatory method must be capable of providing requisite specificity, sensitivity, and quantitative accuracy. At this time gas chromatography/mass spectrometry (GC/MS) is the only recommended confirmation method of choice. All other methods of confirmatory tests must be approved by the County.

INITIAL DRUG TEST - ANABOLIC STEROIDS (URINE): At present the only methodology available for anabolic steroid analysis is gas chromatography/mass spectrometry (GC/MS). To assure reliability, two separate GC/MS analyses will be performed. The first, or initial screen, will distinguish negative specimens from those containing the anabolic steroids or their metabolites.

CONFIRMATORY DRUG TEST - ANABOLIC STEROIDS (URINE): The second, or confirmatory, GC/MS test for anabolic steroids must have a greater sensitivity than the initial screening test. Utilization of a higher sensitivity for the confirmation test is in keeping with Guidelines for Forensic Toxicology.

INTRALABORATORY CHAIN OF CUSTODY: Procedures used by the laboratory to maintain control and accountability from the receipt of specimens until testing is completed and results are reported.

INITIAL ALCOHOL TEST (BREATH): Use of an approved breath alcohol screening device to detect and quantify the presence of alcohol.

INITIAL ALCOHOL TEST (URINE): A chemical enzymatic or immunoassay test of urine to detect the presence of alcohol. To be used when an approved breath alcohol screening device is not available.

CONFIRMATION ALCOHOL TEST (BLOOD): Confirmation testing of blood specimens for blood alcohol shall be performed by gas chromatography or enzymatic methods of quantitative alcohol measurement approved by H.R.S.

RECEIVING/ACCESSION

Upon receipt of specimens, receiving personnel shall inspect packages for evidence of possible tampering and compare information on specimen containers with that on chain of custody forms.

The laboratory shall note on the chain of custody form the time and date of the specimen's arrival to the lab. If any specimen becomes lost, misplaced or is improperly delivered, laboratory personnel shall notify the designated site collection agent immediately. If a package of specimens is received and the outer wrapping is found to be damaged, the laboratory shall note and describe this damage on the chain of custody form. Cold chain time and dates will be reviewed to ensure that not more than 96 hours of unrefrigerated storage/transport has elapsed from time of specimen collection. Out of limit conditions will be noted, and specimens refrigerated as appropriate.

Specimen containers and original chain of custody forms will normally be retained within the receiving area until all analyses have been completed. Chain of custody forms shall be used by laboratory personnel for conducting the initial and confirmatory tests.

SHORT-TERM REFRIGERATED STORAGE

Specimens that do not receive an initial testing on the day of arrival at the laboratory shall be placed in secure, temporary refrigeration units. Temperatures shall not exceed six (6) degrees centigrade. Emergency power equipment should be available in case of prolonged power failure.

SPECIMEN PROCESSING

Drug testing laboratories will normally process specimens by grouping them into batches. The number of specimens in each batch may vary significantly depending on the size of the laboratory and its workload. When conducting either initial or confirmatory testing, every batch shall contain an appropriate number of standards for calibrating the instrumentation and a minimum of 15 percent quality control specimens. Known and blind quality control samples should appear as ordinary samples to laboratory personnel.

INITIAL TEST - OTHER THAN ANABOLIC STEROIDS (URINE)

The initial testing shall use an immunoassay method which meets the requirements of the Food and Drug Administration for commercial distribution. Refer to pages 2 & 3 of this document for details on which drugs should be tested for various categories of employees and applicants. Initial testing for alcohol will be done by means of an approved breath alcohol screening device. If an approved breath alcohol screening device is not available, then urine alcohol testing will be used.

The following cutoff concentrations shall be applicable to determine whether specimens are negative or positive for the following drugs or classes of drugs utilizing the initial test procedure:

	Initial Test Level (ng/ml)
Total Cannabinoid metabolites	40
Total Cocaine metabolites	50

	Initial Test Level (ng/ml)
Opiates	1000
Phencyclidine	25
Barbiturates	300
Benzodiazepines	300

Amphetamines	1000
Methaqualone	750

All individuals will also be tested for alcohol by use of an alcosensor or other approved breath alcohol screening device. A positive result is indicated by the presence of alcohol for reasonable suspicion tests or a quantity of .04% or above for all other tests.

In the event of a positive result, the Collection Site Personnel will draw blood for the drug testing laboratory in accordance with step 15 of the Specimen Collection Section of this document.

CONFIRMATORY TEST - OTHER THAN ANABOLIC STEROIDS (URINE)

All specimens identified as positive by the initial test shall be confirmed using gas chromatography/mass spectrometry (GC/MS) techniques. GC/MS confirmation procedures at the following cutoff concentration shall be used for the following drug:

	Confirmatory Test Level (ng/ml)
Marijuana metabolite*	20
Cocaine metabolite**	20

*Delta-9-tetrahydrocannabinol-9-carboxylic acid
**Benzoylecgonine

For all other drugs listed below the confirmatory test shall detect the confirmed presence of the substance. The laboratory must be prepared to provide evidence from its quality control program to prove its capability of detecting such substances.

Amphetamines
Barbiturates
Benzodiazepines
Methaqualone
Opiates
Phencyclidine

These concentrations are subject to revision with changes in convention or technology. The laboratory must be able to document its performance at the cutoff level by the use of quality control, both open and blind.

Proper chain of custody controls shall always be enforced during confirmation testing. Authorized confirmation technicians shall sign the chain of custody form and be responsible for each urine specimen to be tested. The laboratory shall include sufficient safeguards to ensure that unauthorized personnel are prevented from gaining access to the confirmation laboratory.

INITIAL TEST FOR ANABOLIC STEROIDS (URINE)

The initial testing shall use the gas chromatography/mass spectrometry (GC/MS) techniques. Refer to page 5 of this document for the listing of drugs and their metabolites for which screening will be done. For steroids and metabolites included in the profile, the initial screen will test for the presence of each of the drugs at a sensitivity of 10 ng/ml. The presence of any of the substances at this level shall be taken as a positive result. A testosterone/epitestosterone ratio equal to or greater than 6 to 1 shall be considered a positive result.

CONFIRMATION TEST FOR ANABOLIC STEROIDS (URINE):

All specimens identified as positive by the initial test shall be confirmed using the gas chromatography/mass spectrometry (GC/MS) techniques. For steroids and their metabolites listed on page 5 of this document, confirmatory testing at a sensitivity testing level of 1 ng/ml shall be accomplished.

The laboratory must be able to document its performance at this level by the use of quality control, both open and blind.

Proper chain of custody controls shall always be enforced during confirmation testing. Authorized confirmation technicians shall sign the chain of custody form and be responsible for each urine specimen to be tested. The laboratory shall include sufficient safeguards to ensure that unauthorized personnel are prevented from gaining access to the confirmation laboratory.

CONFIRMATION TEST (BLOOD)

All blood alcohol results shall be reported as gram percent. The cutoff level to determine whether specimens are reported as positive or negative shall be .04% for all tests except reasonable suspicion. For reasonable suspicion, any amount of alcohol shall be reported as positive.

REPORTING RESULTS

Test results shall be reported to the appropriate authority within 3 working days of receipt of the specimens (or other amount of time to be negotiated) unless the Employee Relations Department is notified of problems mandating an extension to this time allotment. The report should contain the specimen number assigned by the collecting site, the testing laboratory reference number, and results of the tests. Quantitative values for positives on the test report are to be included only for cocaine, marijuana and blood alcohol, unless required otherwise. All urine specimens negative on the initial test or negative on the confirmatory test shall be reported as negative. Only specimens confirmed positive shall be reported positive for a specific drug. In the case of pre-employment testing, if the specimen is initially positive for more than one drug, only one drug must be confirmed positive (illegal drugs are first choice, then legal).

The following is the procedure for confirmation tests on legal drugs, excluding alcohol:

1. If positive initial test results of legal drugs, excluding alcohol, are consistent with any over-the-counter or prescription medication the employee or applicant has indicated on the DRUG/ALCOHOL USAGE ANALYSIS CONSENT AND RELEASE FORM, then that

   information should be specified on the toxicology report and no confirmation test GC/MS

should be done without the specific authorization of the County.

2. If no over-the-counter or prescription medication is indicated on the Drug/Alcohol form and there is a positive initial test result indicating the presence of a legal drug other than alcohol, then:
   a. The County Employee Relations Department should be notified of the positive results without any indication of a legal drug from the employee/applicant.
   b. The County Employee Relations Department should contact the employee/ applicant to determine if there was any information inadvertently omitted from the form and supply any new information to the laboratory.
   c. The laboratory will then determine if the new medications indicated are consistent with the positive initial test results.
   d. If information given by the employee/applicant is consistent with the positive initial test results, then that should be specified on the toxicology report and no confirmation test GC/MS should be done without the specific authorization of the County.

3. If the positive initial test results are not consistent with any medications listed by the employee/applicant after following step 2 above, then the GC/MS confirmation test should be performed and the result shall be reported as positive only if confirmed positive by the GC/MS confirmation test.
4. The County reserves the right to authorize a GC/MS confirmation test on any specimen with an initial positive test result notwithstanding any language to the contrary in this procedure.

Results may be transmitted by various electronic means, e.g., teleprinters, facsimile, and computers. Proper security and limited access must be established between the laboratory and user agency or individual. The laboratory or collection site shall not provide results by telephone unless in accordance with developed security procedures. A certified copy of the original chain of custody form for all confirmed positive specimens, signed by the laboratory director or laboratory certifying official, shall be sent to the submitting authority. Certified copies of all analytical results shall be available from the laboratory when requested by appropriate authority.

All records pertaining to a given specimen shall be retained by the drug testing laboratory for a minimum of 5 years.

LONG-TERM STORAGE

Specimens confirmed positive shall be retained and placed in properly secured long-term frozen storage for at least 365 days. Within this 365 day period the submitting authority may request the laboratory to retain the specimen for an additional period of time, or arrange to have the specimen transferred to another site for longer term or permanent storage. This ensures that the urine specimen will be available for a possible retest during any administrative or disciplinary proceeding. If the laboratory does not receive a request to retain the specimen by the end of the initial 365 day period, the specimen may be discarded.

Long term storage facilities shall be equipped with secure locks. Emergency power equipment should be available in case of prolonged power failure. Access to the long term storage facility shall be limited to authorized personnel only.

PAYMENT OF POSTAGE AND FEES

All postage and fees related to information submitted to the County, including forms, reports, etc., shall be prepaid by the laboratory or physical exam contractor.

SUPPLIES AND MATERIALS

All bottles, forms, labels, sealing tape or bags and supplies must be furnished by the laboratory and the physical exam contractor.

RETESTING SPECIMENS

Should specimen reanalysis be required, the quantitation of blood alcohol, non-steroid or steroid drug or drug metabolites should be subjecto to the same testing level criteria that were used during the original analysis. Some analytes deteriorate or are lost during freezing and/or storage, and this information must be

considered when a comparison of results is being attempted. When a retest is requested a third aliquot should be retained for referee analysis in the event of a discrepancy in the analytical findings.

SECURITY

Locks, doors, walls, storage facilities, testing laboratories, and buildings must be resistant to unauthorized entry, tampering, and compromise. Keyed locks must be "tamper-proof", and all cipher locks should be subject to periodic combination changes. All testing and storage areas shall have limited access. In properly established receiving, storage and testing facilities, the construction and physical security construction must be designed either to prevent or detect attempted, forced or surreptitious entry.

REPORTING REQUIREMENTS

The laboratory shall provide the County Employee Relations Department with a monthly statistical summary of blood and urinalysis testing.

Initial testing:

(a) Number of urine specimens received

(b) Number of urine specimens screened positive for the following non-steroid drugs or metabolites:

- Marijuana metabolites
- Opiates (morphine/codeine)
- Barbiturates
- Cocaine metabolites
- Phencyclidine
- Benzodiazepines
- Alcohol
- Amphetamines
- Methaqualone

(c) Number of specimens screened positive for the following anabolic steroid drugs or

metabolites:

Boldenone
Methandienone (Dianabol)
Methyltestosterone
Nandrolone (19-Nortestosterone)
Stanozolol
Epitestosterone
Testosterone
Testosterone/Epitestosterone Ratio
Oxandrolone (Anavar)
Oxymetholone (Anadrol)

Confirmation testing:

(a) Number of urine specimens received
(b) Number of urine specimens confirmed positive for drug tested for (report number of positives for each individual drug)
(c) Number of blood specimens received
(d) Number of blood specimens with detectable blood alcohol reported by range

Less than .04
More than .04 but less than .10
More than .10

SUBCONTRACTING

The drug testing laboratory shall perform all work with its own personnel and equipment, unless otherwise authorized by the County.

LABORATORY FACILITIES

Laboratories must be currently certified by the National Institute on Drug Abuse (NIDA) and licensed by the Florida Department of HRS in Clinical Chemistry if located in Florida or by the federal government under C.L.I.A. if located outside Florida and must comply with any applicable provisions of the Clinical Laboratory Improvement Act (CLIA) of 1967. Licensed laboratories must have the facility and capability, at the same laboratory, of performing confirmation tests for alcohol and for each drug and/or drug metabolite required by the County. Accredited laboratories must have the facility and capability, at the same laboratory, of performing confirmation tests for alcohol and for each drug and/or drug metabolite included in tests 1,2, and 3 and required by the user agencies of Miami Dade County.

LABORATORY PERSONNEL

The scientific director of the drug testing laboratory shall be qualified to assume professional, organizational, educational, and administrative responsibility for the laboratory. This director is an individual with documented scientific qualifications comparable to those of a person certified by the American Board of Forensic Toxicology or the American Board of Clinical Chemistry in Toxicological Chemistry. Acceptable qualifications include a Ph.D. in either pharmacology, toxicology or analytical chemistry followed by at least two years experience in analytical toxicology (the analysis of biological material for drugs of abuse) and appropriate training and/or forensic applications of analytical toxicology (court testimony, research and publications in analytical toxicology of drugs of abuse, etc.) The director is responsible for ensuring that there are sufficient personnel with adequate training and

experience to supervise and conduct the work of the blood alcohol and urine drug testing laboratory.

A key individual in this laboratory is the certifying scientist; the one who reviews the standards, control specimens, and quality control data together with the screening and confirmation test results. After having assured that all results are acceptable, this individual certifies the test result. The certifying scientist may be the laboratory scientific director but in any event must have sound training in the sciences, specific training in the theory and practice of the procedures used, including the recognition of aberrant results, and familiarity with quality control procedures.

Supervisors of analysts must be currently licensed as supervisors in Clinical Chemistry and must possess the education and experience required for such licensure. These individuals also must have training in the theory and practice of the procedures used, and understanding of quality control concepts. Periodic verification of their skills must be documented. Other technicians must be licensed in clinical chemistry according to the category technologist or technician. Nontechnical staff must possess the necessary training and skills for the tasks assigned. In-service continuing education programs to meet the needs of all laboratory personnel are desirable. Personnel files must include: resume of training and experience, certification or license, if any, references, job descriptions, records of performance evaluation and advancement.

The County reserves the right to require background checks on laboratory personnel and to approve those personnel who will perform work related to the County's testing program.

QUALITY ASSURANCE AND QUALITY CONTROL

Laboratories performing blood alcohol or urine drug testing shall have a quality assurance program which encompasses all aspects of the testing process: specimen acquisition, chain of custody, security, and reporting results, in addition to the screening and confirmation of analytical procedures. Quality control procedures will be designed, implemented and reviewed to monitor the conduct of each step of the process.

Quality Control (QC) urine specimens containing no drug and specimens fortified with known standard shall be analyzed with each batch of specimens screened. Some of these will be blind to the analyst. In addition, some of these QC specimens will contain drug or metabolite at or near the threshold (cutoff) levels. Similar controls will be analyzed in parallel with confirmation test. Implementation of procedures must be documented to ensure that carry-over does not contaminate the testing of a subject's specimen. A minimum of 15 percent of all test samples must be QC or external proficiency specimens. Similar procedures for blood alcohol confirmation testing will be used with standard specimens and quality controls representing a minimum of 15% QC of all Blood Confirmation tested.

Participation in proficiency testing surveys, by which the laboratory performance is compared with peers and reference laboratories, is mandatory. Participation in the ADAMHA/National Institute on Drug Abuse (NIDA)-recognized proficiency testing program for drugs of abuse is required. Any unsatisfactory proficiency testing result must be investigated and corrective measure initiated. A report of the investigative findings, together with subsequent corrective actions, should be recorded, dated and signed by the responsible supervisor and laboratory director. Continued and/or uncorrected unsatisfactory performance on recognized proficiency test samples may be sufficient cause for loss of accreditation.

DOCUMENTATION

Documentation of all aspects of the testing process must be available. This documentation will be maintained for at least 5 years and will include: personnel files on analysts, supervisors, directors, and all individuals authorized to have access to specimens; chain of custody documents; quality assurance/quality control records; all test data; reports; performance records on proficiency testing; performance on accreditation inspections once available; and hard copies of computer-generated data.

REPORTS

All test results, including screening, confirmation, and quality control data must be reviewed by the certifying scientist or laboratory director before a test result is certified as accurate. For blood specimens, the detected concentration of blood alcohol shall be reported. For urine specimens, the report shall provide the drug/metabolites which tested confirmed positive, and in the cases of marijuana and cocaine, the quantitative values of the positive results.

INSPECTIONS

Miami-Dade County shall reserve the right to inspect the laboratory and review the personnel records of the laboratory at any time. Contracts with laboratories, as well as for collection site services, shall permit unannounced inspections.

PRE AWARD INSPECTION

The County reserves the right to conduct pre and post award inspections and/or to require other evidence of technical, managerial, financial, and similar abilities to perform the work described in these specifications. These inspections may include testing quality control samples, a survey of the laboratory buildings, facilities, security, critical personnel, and the overall capacity to conform to all of these guidelines.

DRUG PROGRAM OFFICER

The drug program officer is responsible for the monitoring of the laboratory's work. The responsibilities include but are not limited to: inspection of laboratory work to ensure compliance with these guidelines, documentation through written inspection reports of all results of the inspections conducted, follow up to assure that all defects or omissions are rectified, and conferences with representatives of the laboratory regarding any problems in the performance of the work. The County may combine the duties of the drug program officer with those of the contract or administrative officer having overall responsibility for the County drug testing program.

JUDICIAL PROCEEDINGS

The laboratory must have qualified personnel available to testify in any judicial, administrative or disciplinary proceeding against any employee that is based on a blood alcohol report or a positive urinalysis result reported by its laboratory. The laboratory must submit to the County a complete resume of employees whom the laboratory believes are most likely to be called to testify. Qualified laboratory personnel must also be available to meet with County representatives to discuss testimony

related to any of the above proceedings.

FACILITIES

The laboratory must be made available for inspection by County Officials at any time during normal working hours.

REPORTING AND REVIEW OF RESULTS

An essential part of the alcohol and drug testing program is the final review of results. A positive test result does not automatically identify an employee/applicant as an alcohol abuser or an illegal drug user.

URINE SPECIMENS

In all cases where there is a positive, confirmed drug test, and there is a medication history provided to the laboratory for that specimen in which the drug detected is the same as the drug reported on the medication history, the report will be forwarded to the medical review officer (MRO) of the submitting authority. The MRO may be within the Miami-Dade County workforce, or contracted with to provide this service. The MRO
will be a licensed physician with knowledge of substance abuse disorders. The role of the MRO will be to review positive findings received from the laboratory when there is the possibility that there may be a legitimate medical basis for the positive laboratory test. The MRO will take whatever actions are necessary e.g. contact with the individual that provided the specimen, examination of prescription containers, contact with the prescribing physician, or other actions deemed professionally necessary. The MRO will then make a decision regarding the medical interpretation of the positive laboratory finding. The findings shall include one of the following: 1) medically substantiated (MS) and reported as such to the submitting authority. 2) not medically substantiated (NMS) reporting the test as a positive laboratory result with a notation of medical review to the submitting authority. 3) request reanalysis of the specimen in the Laboratory, together with discussion regarding the case between experts in the laboratory and elsewhere. A final determination shall be made at the end of this process as to medically substantiated or not medically substantiated.

PROTECTION OF EMPLOYEE AND JOB APPLICANT RECORDS

Any laboratory contract shall provide that the contractor's records are to be kept confidential to the extent permissible under Florida's Public Records Act, Florida Statute Chapter 119. Miami-Dade County shall establish a system of maintaining records to cover
both the County's and the contractor's records of applicant and employee urinalysis and blood alcohol results. The contract and the record maintenance system must have specific provisions that require that employee records are maintained and used with the highest regard for employee privacy consistent with Florida's Public Records Act and the purpose of achieving and maintaining an alcohol abuse and drug-free workplace.

EVALUATION FACTORS FOR APPROVAL

EVALUATION CRITERIA - COLLECTION SITE

The County must consider the following elements when evaluating collection sites (Physical Exam

Providers):

(1) OPERATING PLANS - to be evaluated on the basis of work as demonstrated by internal control and execution of assigned work, including compliance with all Specimen Collection Procedures, Collection Control and Transportation to the Laboratory.

(2) LABORATORY - to be evaluated on the basis of the contract between the Physical Exam Provider and a Laboratory which meets all the requirements of this Scientific and Administrative Protocol document and which is approved as such by the County.

(3) KEY PERSONNEL - to be evaluated on the appropriateness of positions and qualifications and skills designated for those employees acting as collection site agents and performing the duties described in this document.

(4) QUALITY ASSURANCE AND CONTROL PROGRAM - to be evaluated on the basis of proposed methods and techniques for the detection and correction of deficiencies with regard to Specimen Collection Procedures, Collection Control and Transportation to the Laboratory.

(5) FACILITIES - to be evaluated on the basis of proper facilities for collection, temporary storage, and transportation of specimens.

EVALUATION CRITERIA – LABORATORY

The County must consider the following elements when evaluating laboratories:

(1) OPERATING PLANS - to be evaluated on the basis of work, as demonstrated by internal control and execution of assigned work, including proper receiving, storage, internal chain of custody, testing, supervision, security, and plans for reporting test results to the County as required.

(2) COMPANY EXPERIENCE - to be evaluated on the basis of total years of relevant laboratory experience in providing similar services as verified through references of past and present performance.

(3) TEST METHODS - to be evaluated on the basis of the scientific acceptability of the actual methods to be employed, the proper inclusion of standards, and evaluation of previous test records.

(4) KEY PERSONNEL - to be evaluated on the basis of the appropriateness of positions and skills designated by the laboratory, the qualifications proposed, the certifications obtained, and the submission of specific nominations for key personnel.

(5) QUALITY ASSURANCE AND CONTROL PROGRAM - to be evaluated on the basis of the proposed methods and techniques for the detection and correction of deficiencies with regard to receiving, chain of custody, preliminary/confirmation testing and storage.

(6) FACILITIES - to be evaluated on the basis of laboratory facilities and equipment for receiving, testing, security, and storage of blood and urine specimens.

ATTACHMENT D

PROTOCOL

Miami-Dade County Employee's Medical Assessment and Testing Procedures

Fitness for Duty Physical Examination

This physical examination may include all of the requirements of a High-Stress Physical Examination. Additional tests may be ordered at the physician's request to assist his evaluation of the patient.

Physicals of this nature will be authorized when the department has concerns about the employee's physical ability to perform his/her job. The purpose of the physical is to evaluate the employee's physical condition and make a recommendation to the County of the employee's ability or inability to perform the job to which he/she is currently assigned. This physical shall include a consultation with the employee's private physician, a review of the employee's medical records, and an examination of the employee. Any special laboratory tests or x-rays shall be recommended to the County Human Resources Department for approval, and scheduled and conducted within 2 days of the County's approval.

A narrative report of the findings and recommendations shall be submitted to the County Human Resources Department within 5 business days of the completion of the examination of the employee. Liquidated damages in the amount of $ 100.00 per day will be charged for any Fitness for Duty examination for which a report is received later than 5 days after the date of the examination.

NOTE:

ALL TESTS ORDERED MUST BE APPROVED BY THE COUNTY HUMAN RESOURCES DEPARTMENT, BEFORE INITIATION.

ATTACHMENT E

PROTOCOL

Miami-Dade County Employee's Medical Assessment and Testing Procedures

MEDICAL SURVEILLANCE PROGRAM AND EXPOSERE TESTING REQUIRED BY OSHA

All physical examinations standards and tests required by this protocol will be found in the Title 29 Code of Federal Regulations (CFR) Part 1910.

OSHA STANDARDS REQUIRING MEDICAL SURVELLANCE:

1) TB

2) Access to employee exposure and medical records

3) Noise

4) Laboratories

5) Ionizing Radiation

6) Bloodborne Pathogens

7) Carginogens

8) Lead

9) Asbestos

10) Formaldehyde

11) Others

MEDICAL HISTORY SHEET

Examinee will complete a family and personal medical history to be reviewed by the physician with him/her at time of physical exam. The medical history sheet should include the following:

A. Past medical history
B. Past surgical history
C. Past immunizations
D. Family History
E. Occupational History
F. Habits
G. Exercise Habits
H. Review of Systems

LABORATORY/BIOLOGICAL WORK-UP AND VACCINES:

HAZMAT TESTING

HEAVY METALS TESTING

CHOLENESTEREASE TESTING

LEAD AND ZINC PROTOPORPHYRIN TESTING

HEPATITIS B TESTING

HIV TESTING

POST EXPOSURE BLOODBORNE PATHOGEN TESTING AND VACCINES

BLOOD GAS TESTING

HEPATITIS A TESTING

HEPATITIS C TESTING

All medical evaluations must be completed by a physician and will include a written medical summary and interpretation.

ATTACHMENT F

P R O T O C O L

Miami-Dade County Employee's Medical Assessment and Testing Procedures

THE DEPARTMENT OF TRANSPORTATION DRUG AND ALCOHOL TESTING PROGRAMS

All testing and collection procedures required by this protocol will be found in the following Codes of Federal Regulations (CFR) Title 49:

1) Title 49 CFR Part 40, Procedures For Transportation Workplace Drug and Alcohol Testing Programs

2) Title 49 CFR Part 655 - Prevention of Alcohol Misuse and Prohibited Drug Use in Transit Operations

3) Title 49 CFR Part 382 - Controlled Substances and Alcohol Use and Testing

Program also requires the following services:

Medical Review Officer(s)

Breath Alcohol Technician(s)

Drug/Alcohol Collection

ATTACHMENT F-1

P R O T O C O L

Miami-Dade County Employee's Medical Assessment and Testing Procedures

PART 40 - PROCEDURES FOR TRANSPORTATION WORKPLACE DRUG AND ALCOHOL TESTING PROGRAMS

TITLE 49: TRANSPORTATION

PART 40 - PROCEDURES FOR TRANSPORTATION WORKPLACE DRUG AND ALCOHOL TESTING PROGRAMS
(Updated as of February 25, 2010)

Reprinted by the Department of Transportation, Drug and Alcohol Policy and Compliance Office,
1200 New Jersey Avenue, SE, Washington, DC 20590 (202) 366-3784

Subpart A - Administrative Provisions

§ 40.1 Who does this regulation cover?
§ 40.3 What do the terms used in this regulation mean?
§ 40.5 Who issues authoritative interpretations of this regulation?
§ 40.7 How can you get an exemption from a requirement in this regulation?

Subpart B - Employer Responsibilities

§ 40.11 What are the general responsibilities of employers under this regulation?
§ 40.13 How do DOT drug and alcohol tests relate to non-DOT tests?
§ 40.15 May an employer use a service agent to meet DOT drug and alcohol testing requirements?
§ 40.17 Is an employer responsible for obtaining information from its service agents?
§ 40.19 [Reserved]
§ 40.21 May an employer stand down an employee before the MRO has completed the verification process?
§ 40.23 What actions do employers take after receiving verified test results?
§ 40.25 Must an employer check on the drug and alcohol testing record of employees it is intending to use to perform safety-sensitive duties?
§ 40.26 What form must an employer use to report Management Information System (MIS) data to a DOT agency?
§ 40.27 May an employer require an employee to sign a consent or release in connection with the DOT drug and alcohol testing program?
§ 40.29 Where is other information on employer responsibilities found in this regulation?

Subpart C - Urine Collection Personnel

§ 40.31 Who may collect urine specimens for DOT drug testing?
§ 40.33 What training requirements must a collector meet?
§ 40.35 What information about the DER must employers provide to collectors?
§ 40.37 Where is other information on the role of collectors found in this regulation?

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

§ 40.41 Where does a urine collection for a DOT drug test take place?
§ 40.43 What steps must operators of collection sites take to protect the security and integrity of urine collections?
§ 40.45 What form is used to document a DOT urine collection?
§ 40.47 May employers use the CCF for non-Federal collections or non-Federal forms for DOT collections?
§ 40.49 What materials are used to collect urine specimens?
§ 40.51 What materials are used to send urine specimens to the laboratory?

Subpart E - Urine Specimen Collections

§ 40.61 What are the preliminary steps in the collection process?
§ 40.63 What steps does the collector take in the collection process before the employee provides a urine specimen?
§ 40.65 What does the collector check for when the employee presents a specimen?
§ 40.67 When and how is a directly observed collection conducted?
§ 40.69 How is a monitored collection conducted?
§ 40.71 How does the collector prepare the specimens?
§ 40.73 How is the collection process completed?

Subpart F - Drug Testing Laboratories

§ 40.81 What laboratories may be used for DOT drug testing?
§ 40.83 How do laboratories process incoming specimens?
§ 40.85 What drugs do laboratories test for?
§ 40.87 What are the cutoff concentrations for initial and confirmation tests?
§ 40.89 What is validity testing, and are laboratories required to conduct it?
§ 40.91 What validity tests must laboratories conduct on primary specimens?
§ 40.93 What criteria do laboratories use to establish that a specimen is dilute or substituted?
§ 40.95 What are the adulterant cutoff concentrations for initial and confirmation tests?
§ 40.96 What criteria do laboratories use to establish that a specimen is invalid?
§ 40.97 What do laboratories report and how do they report it?
§ 40.99 How long does the laboratory retain specimens after testing?
§ 40.101 What relationship may a laboratory have with an MRO?
§ 40.103 What are the requirements for submitting blind specimens to a laboratory?
§ 40.105 What happens if the laboratory reports a result different from that expected for a blind specimen?
§ 40.107 Who may inspect laboratories?
§ 40.109 What documentation must the laboratory keep, and for how long?
§ 40.111 When and how must a laboratory disclose statistical summaries and other information it maintains?
§ 40.113 Where is other information concerning laboratories found in this regulation?

Subpart G - Medical Review Officers and the Verification Process

§ 40.121 Who is qualified to act as an MRO?
§ 40.123 What are the MRO's responsibilities in the DOT drug testing program?
§ 40.125 What relationship may an MRO have with a laboratory?
§ 40.127 What are the MRO's functions in reviewing negative test results?
§ 40.129 What are the MRO's functions in reviewing laboratory confirmed non-negative drug test results?
§ 40.131 How does the MRO or DER notify an employee of the verification process after receiving laboratory confirmed non-negative drug test results?
§ 40.133 Without interviewing the employee, under what circumstances may the MRO verify a test result as positive, or as a refusal to test because of adulteration or substitution, or as cancelled because the test was invalid?
§ 40.135 What does the MRO tell the employee at the beginning of the verification interview?
§ 40.137 On what basis does the MRO verify test results involving marijuana, cocaine, amphetamines, or PCP?
§ 40.139 On what basis does the MRO verify test results involving opiates?
§ 40.141 How does the MRO obtain information for the verification decision?
§ 40.143 [Reserved]
§ 40.145 On what basis does the MRO verify test results involving adulteration or substitution?

§ 40.147 [Reserved]
§ 40.149 May the MRO change a verified drug test result?
§ 40.151 What are MROs prohibited from doing as part of the verification process?
§ 40.153 How does the MRO notify employees of their right to a test of the split specimen?
§ 40.155 What does the MRO do when a negative or positive test result is also dilute?
§ 40.157 [Reserved]
§ 40.159 What does the MRO do when a drug test result is invalid?
§ 40.160 What does the MRO do when a valid result cannot be produced and a negative result is required?
§ 40.161 What does the MRO do when a drug test specimen is rejected for testing?
§ 40.162 What must MROs do with multiple verified results for the same testing event?
§ 40.163 How does the MRO report drug test results?
§ 40.165 To whom does the MRO transmit reports of drug test results?
§ 40.167 How are MRO reports of drug results transmitted to the employer?
§ 40.169 Where is other information concerning the role of MROs and the verification process found in this regulation?

Subpart H - Split Specimen Tests

§ 40.171 How does an employee request a test of a split specimen?
§ 40.173 Who is responsible for paying for the test of a split specimen?
§ 40.175 What steps does the first laboratory take with a split specimen?
§ 40.177 What does the second laboratory do with the split specimen when it is tested to reconfirm the presence of a drug or drug metabolite?
§ 40.179 What does the second laboratory do with the split specimen when it is tested to reconfirm an adulterated test result?
§ 40.181 What does the second laboratory do with the split specimen when it is tested to reconfirm a substituted test result?
§ 40.183 What information do laboratories report to MROs regarding split specimen results?
§ 40.185 Through what methods and to whom must a laboratory report split specimen results?
§ 40.187 What does the MRO do with split specimen laboratory results?
§ 40.189 Where is other information concerning split specimens found in this regulation?

Subpart I - Problems in Drug Tests

§ 40.191 What is a refusal to take a DOT drug test, and what are the consequences?
§ 40.193 What happens when an employee does not provide a sufficient amount of urine for a drug test?
§ 40.195 What happens when an individual is unable to provide a sufficient amount of urine for a pre-employment follow-up or return-to-duty test because of a permanent or long-term medical condition?
§ 40.197 What happens when an employer receives a report of a dilute specimen?
§ 40.199 What problems always cause a drug test to be cancelled?
§ 40.201 What problems always cause a drug test to be cancelled and may result in a requirement for another collection?
§ 40.203 What problems cause a drug test to be cancelled unless they are corrected?
§ 40.205 How are drug test problems corrected?
§ 40.207 What is the effect of a cancelled drug test?
§ 40.208 What problem requires corrective action but does not result in the cancellation of a test?
§ 40.209 What procedural problems do not result in the cancellation of a test and do not require corrective action?

Subpart J - Alcohol Testing Personnel

§ 40.211 Who conducts DOT alcohol tests?
§ 40.213 What training requirements must STTs and BATs meet?
§ 40.215 What information about the DER do employers have to provide to BATs and STTs?
§ 40.217 Where is other information on the role of STTs and BATs found in this regulation?

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

§ 40.221 Where does an alcohol test take place?
§ 40.223 What steps must be taken to protect the security of alcohol testing sites?
§ 40.225 What form is used for an alcohol test?
§ 40.227 May employers use the ATF for non-DOT tests, or non-DOT forms for DOT tests?
§ 40.229 What devices are used to conduct alcohol screening tests?
§ 40.231 What devices are used to conduct alcohol confirmation tests?
§ 40.233 What are the requirements for proper use and care of EBTs?
§ 40.235 What are the requirements for proper use and care of ASDs?

Subpart L - Alcohol Screening Tests

§ 40.241 What are the first steps in any alcohol screening test?
§ 40.243 What is the procedure for an alcohol screening test using an EBT or non-evidential breath ASD?
§ 40.245 What is the procedure for an alcohol screening test using a saliva ASD or a breath tube ASD?
§ 40.247 What procedures does the BAT or STT follow after a screening test result?

Subpart M - Alcohol Confirmation Tests

§ 40.251 What are the first steps in an alcohol confirmation test?
§ 40.253 What are the procedures for conducting an alcohol confirmation test?
§ 40.255 What happens next after the alcohol confirmation test result?

Subpart N - Problems in Alcohol Testing

§ 40.261 What is a refusal to take an alcohol test, and what are the consequences?
§ 40.263 What happens when an employee is unable to provide a sufficient amount of saliva for an alcohol screening test?
§ 40.265 What happens when an employee is unable to provide a sufficient amount of breath for an alcohol test?
§ 40.267 What problems always cause an alcohol test to be cancelled?
§ 40.269 What problems cause an alcohol test to be cancelled unless they are corrected?
§ 40.271 How are alcohol testing problems corrected?
§ 40.273 What is the effect of a cancelled alcohol test?
§ 40.275 What is the effect of procedural problems that are not sufficient to cancel an alcohol test?
§ 40.277 Are alcohol tests other than saliva or breath permitted under these regulations?

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

§ 40.281 Who is qualified to act as a SAP?
§ 40.283 How does a certification organization obtain recognition for its members as SAPs?
§ 40.285 When is a SAP evaluation required?
§ 40.287 What information is an employer required to provide concerning SAP services to an employee who has a DOT drug and alcohol regulation violation?
§ 40.289 Are employers required to provide SAP and treatment services to employees?
§ 40.291 What is the role of the SAP in the evaluation, referral, and treatment process of an employee who has

violated DOT agency drug and alcohol testing regulations?
§ 40.293 What is the SAP's function in conducting the initial evaluation of an employee?
§ 40.295 May employees or employers seek a second SAP evaluation if they disagree with the first SAP's recommendations?
§ 40.297 Does anyone have the authority to change a SAP's initial evaluation?
§ 40.299 What is the SAP's role and what are the limits on a SAP's discretion in referring employees for education and treatment?
§ 40.301 What is the SAP's function in the follow-up evaluation of an employee?
§ 40.303 What happens if the SAP believes the employee needs additional treatment, aftercare, or support group services even after the employee returns to safety-sensitive duties?
§ 40.305 How does the return-to-duty process conclude?
§ 40.307 What is the SAP's function in prescribing the employee's follow-up tests?
§ 40.309 What are the employer's responsibilities with respect to the SAP's directions for follow-up tests?
§ 40.311 What are the requirements concerning SAP reports?
§ 40.313 Where is other information on SAP functions and the return-to-duty process found in this regulation?

Subpart P - Confidentiality and Release of Information
§ 40.321 What is the general confidentiality rule for drug and alcohol test information?
§ 40.323 May program participants release drug or alcohol test information in connection with legal proceedings?
§ 40.325 [Reserved]
§ 40.327 When must the MRO report medical information gathered in the verification process?
§ 40.329 What information must laboratories, MROs, and other service agents release to employees?
§ 40.331 To what additional parties must employers and service agents release information?
§ 40.333 What records must employers keep?

Subpart Q - Roles and Responsibilities of Service Agents
§ 40.341 Must service agents comply with DOT drug and alcohol testing requirements?
§ 40.343 What tasks may a service agent perform for an employer?
§ 40.345 In what circumstances may a C/TPA act as an intermediary in the transmission of drug and alcohol testing information to employers?
§ 40.347 What functions may C/TPAs perform with respect to administering testing?
§ 40.349 What records may a service agent receive and maintain?
§ 40.351 What confidentiality requirements apply to service agents?
§ 40.353 What principles govern the interaction between MROs and other service agents?
§ 40.355 What limitations apply to the activities of service agents?

Subpart R - Public Interest Exclusions
§ 40.361 What is the purpose of a public interest exclusion (PIE)?
§ 40.363 On what basis may the Department issue a PIE?
§ 40.365 What is the Department's policy concerning starting a PIE proceeding?
§ 40.367 Who initiates a PIE proceeding?
§ 40.369 What is the discretion of an initiating official in starting a PIE proceeding?
§ 40.371 On what information does an initiating official rely in deciding whether to start a PIE proceeding?
§ 40.373 Before starting a PIE proceeding, does the initiating official give the service agent an opportunity to correct problems?
§ 40.375 How does the initiating official start a PIE proceeding?
§ 40.377 Who decides whether to issue a PIE?
§ 40.379 How do you contest the issuance of a PIE?

§ 40.381 What information do you present to contest the proposed issuance of a PIE?
§ 40.383 What procedures apply if you contest the issuance of a PIE?
§ 40.385 Who bears the burden of proof in a PIE proceeding?
§ 40.387 What matters does the Director decide concerning a proposed PIE?
§ 40.389 What factors may the Director consider?
§ 40.391 What is the scope of a PIE?
§ 40.393 How long does a PIE stay in effect?
§ 40.395 Can you settle a PIE proceeding?
§ 40.397 When does the Director make a PIE decision?
§ 40.399 How does the Department notify service agents of its decision?
§ 40.401 How does the Department notify employers and the public about a PIE?
§ 40.403 Must a service agent notify its clients when the Department issues a PIE?
§ 40.405 May the Federal courts review PIE decisions?
§ 40.407 May a service agent ask to have a PIE reduced or terminated?
§ 40.409 What does the issuance of a PIE mean to transportation employers?
§ 40.411 What is the role of the DOT Inspector General's office?
§ 40.413 How are notices sent to service agents?

Appendix A to Part 40 - DOT Standards for Urine Collection Kits
Appendix B to Part 40 - DOT Drug Testing Semi-Annual Laboratory Report to Employers
Appendix C to Part 40 - DOT Drug Testing Semi-Annual Laboratory Report to DOT
Appendix D to Part 40 - Report Format: Split Specimen Failure to Reconfirm
Appendix E to Part 40 - SAP Equivalency Requirements for Certification Organizations
Appendix F to Part 40 - Drug and Alcohol Testing Information that C/TPAs May Transmit to Employers
Appendix G to Part 40 - Alcohol Testing Form
Appendix H to Part 40 - DOT Drug and Alcohol Testing Management Information System (MIS) Data Collection Form

Authority: 49 U.S.C. 102, 301, 322, 5331, 20140, 31306, and 45101 et seq.
Source: 65 FR 79526, Dec. 19, 2000, unless otherwise noted.

Subpart A - Administrative Provisions

§ 40.1 Who does this regulation cover?

(a) This part tells all parties who conduct drug and alcohol tests required by Department of Transportation (DOT) agency regulations how to conduct these tests and what procedures to use.

(b) This part concerns the activities of transportation employers, safety-sensitive transportation employees (including self-employed individuals, contractors and volunteers as covered by DOT agency regulations), and service agents.

(c) Nothing in this part is intended to supersede or conflict with the implementation of the Federal Railroad Administration's post-accident testing program (see 49 CFR 219.200).

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

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

Adulterated specimen. A urine specimen containing a substance that is not a normal constituent or containing an endogenous substance at a concentration that is not a normal physiological concentration.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Confirmatory drug test. A second analytical procedure to identify the presence of a specific drug or metabolite which is independent of the initial test and which uses a different technique and chemical principle from that of the initial test in order to ensure reliability and accuracy. (Gas chromatography/ mass spectrometry (GC/MS) is the only authorized confirmation method for cocaine, marijuana, opiates, amphetamines, and phencyclidine).

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

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

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

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

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

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

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

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

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

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

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

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

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

Initial drug test (also known as a Screening drug test). An immunoassay test to eliminate "negative" urine specimens from further consideration and to identify the presumptively positive specimens that require confirmation or further testing.

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

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

Laboratory. Any U.S. laboratory certified by HHS under the National Laboratory Certification Program as meeting the minimum standards of Subpart C of the HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs; or, in the case of foreign laboratories, a laboratory approved for participation by DOT under this part. (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)

Limit of Detection (LOD). The lowest concentration at which an analyte can be reliably shown to be present under defined conditions.

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.

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

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

Oxidizing adulterant. A substance that acts alone or in combination with other substances to oxidize drugs or drug metabolites to prevent the detection of the drug or drug metabolites, or affects the reagents in either the initial or confirmatory drug test.

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

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

Refresher Training. The training required periodically for qualified collectors, BATs, and STTs to review basic requirements and provide instruction concerning changes in technology (e.g., new testing methods that may be authorized) and amendments, interpretations, guidance, and issues concerning this part and DOT

agency drug and alcohol testing regulations. Refresher training can be provided by any appropriate means (e.g., classroom instruction, internet application, CD–ROM, video).

Screening Drug Test. See Initial drug test definition above.

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

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

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

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

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

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

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

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

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

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

[65 FR 79526, Dec. 19, 2000, as amended at 66 FR 41950, Aug. 9, 2001; 71 FR 49384, August 23, 2006; 71 FR 55347, Sept. 22, 2006; 73 FR 35969, June 25, 2008]

§ 40.5 Who issues authoritative interpretations of this regulation?

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

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

(a) If you want an exemption from any provision of this part, you must request it in writing from the Office of the Secretary of Transportation, under the provisions and standards of 49 CFR part 5. You must send requests for an exemption to the following address: Department of Transportation, Deputy Assistant General Counsel for Regulation and Enforcement, 1200 New Jersey Avenue, SE, Washington, DC 20590.

(b) Under the standards of 49 CFR part 5, we will grant the request only if the request documents special or exceptional circumstances, not likely to be generally applicable and not contemplated in connection with the

rulemaking that established this part, that make your compliance with a specific provision of this part impracticable.

(c) If we grant you an exemption, you must agree to take steps we specify to comply with the intent of the provision from which an exemption is granted.

(d) We will issue written responses to all exemption requests.

[65 FR 79526, Dec. 19, 2000, as amended at 73 FR 33329, June 12, 2008]

Subpart B - Employer Responsibilities

§ 40.11 What are the general responsibilities of employers under this regulation?

(a) As an employer, you are responsible for meeting all applicable requirements and procedures of this part.

(b) You are responsible for all actions of your officials, representatives, and agents (including service agents) in carrying out the requirements of the DOT agency regulations.

(c) All agreements and arrangements, written or unwritten, between and among employers and service agents concerning the implementation of DOT drug and alcohol testing requirements are deemed, as a matter of law, to require compliance with all applicable provisions of this part and DOT agency drug and alcohol testing regulations. Compliance with these provisions is a material term of all such agreements and arrangements.

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

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

(b) DOT tests must take priority and must be conducted and completed before a non-DOT test is begun. For example, you must discard any excess urine left over from a DOT test and collect a separate void for the subsequent non-DOT test.

(c) Except as provided in paragraph (d) of this section, you must not perform any tests on DOT urine or breath specimens other than those specifically authorized by this part or DOT agency regulations. For example, you may not test a DOT urine specimen for additional drugs, and a laboratory is prohibited from making a DOT urine specimen available for a DNA test or other types of specimen identity testing.

(d) The single exception to paragraph (c) of this section is when a DOT drug test collection is conducted as part of a physical examination required by DOT agency regulations. It is permissible to conduct required medical tests related to this physical examination (e.g., for glucose) on any urine remaining in the collection container after the drug test urine specimens have been sealed into the specimen bottles.

(e) No one is permitted to change or disregard the results of DOT tests based on the results of non-DOT tests. For example, as an employer you must not disregard a verified positive DOT drug test result because the employee presents a negative test result from a blood or urine specimen collected by the employee's physician or a DNA test result purporting to question the identity of the DOT specimen.

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

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

(a) As an employer, you may use a service agent to perform the tasks needed to comply with this part and DOT agency drug and alcohol testing regulations, consistent with the requirements of Subpart Q and other applicable provisions of this part.

(b) As an employer, you are responsible for ensuring that the service agents you use meet the qualifications set forth in this part (e.g., §40.121 for MROs). You may require service agents to show you documentation that they meet the requirements of this part (e.g., documentation of MRO qualifications required by §40.121(e)).

(c) You remain responsible for compliance with all applicable requirements of this part and other DOT drug and alcohol testing regulations, even when you use a service agent. If you violate this part or other DOT

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

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

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

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

§ 40.19 [Reserved]

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

(a) As an employer, you are prohibited from standing employees down, except consistent with a waiver a DOT agency grants under this section.

(b) You may make a request to the concerned DOT agency for a waiver from the prohibition of paragraph (a) of this section. Such a waiver, if granted, permits you to stand an employee down following the MRO's receipt of a laboratory report of a confirmed positive test for a drug or drug metabolite, an adulterated test, or a substituted test pertaining to the employee.

(1) For this purpose, the concerned DOT agency is the one whose drug and alcohol testing rules apply to the majority of the covered employees in your organization. The concerned DOT agency uses its applicable procedures for considering requests for waivers.

(2) Before taking action on a waiver request, the concerned DOT agency coordinates with other DOT agencies that regulate the employer's other covered employees.

(3) The concerned DOT agency provides a written response to each employer that petitions for a waiver, setting forth the reasons for the agency's decision on the waiver request.

(c) Your request for a waiver must include, as a minimum, the following elements:

(1) Information about your organization:

(i) Your determination that standing employees down is necessary for safety in your organization and a statement of your basis for it, including any data on safety problems or incidents that could have been prevented if a stand-down procedure had been in place;

(ii) Data showing the number of confirmed laboratory positive, adulterated, and substituted test results for your employees over the two calendar years preceding your waiver request, and the number and percentage of those test results that were verified positive, adulterated, or substituted by the MRO;

(iii) Information about the work situation of the employees subject to stand-down, including a description of the size and organization of the unit(s) in which the employees work, the process through which employees will be informed of the stand-down, whether there is an in-house MRO, and whether your organization has a medical disqualification or stand-down policy for employees in situations other than drug and alcohol testing; and

(iv) A statement of which DOT agencies regulate your employees.

(2) Your proposed written company policy concerning stand-down, which must include the following elements:

(i) Your assurance that you will distribute copies of your written policy to all employees that it covers;

(ii) Your means of ensuring that no information about the confirmed positive, adulterated, or substituted test result or the reason for the employee's temporary removal from performance of safety-sensitive functions

becomes available, directly or indirectly, to anyone in your organization (or subsequently to another employer) other than the employee, the MRO and the DER;

(iii) Your means of ensuring that all covered employees in a particular job category in your organization are treated the same way with respect to stand-down;

(iv) Your means of ensuring that a covered employee will be subject to stand-down only with respect to the actual performance of safety-sensitive duties;

(v) Your means of ensuring that you will not take any action adversely affecting the employee's pay and benefits pending the completion of the MRO's verification process. This includes continuing to pay the employee during the period of the stand-down in the same way you would have paid him or her had he or she not been stood down;

(vi) Your means of ensuring that the verification process will commence no later than the time an employee is temporarily removed from the performance of safety-sensitive functions and that the period of stand-down for any employee will not exceed five days, unless you are informed in writing by the MRO that a longer period is needed to complete the verification process; and

(vii) Your means of ensuring that, in the event that the MRO verifies the test negative or cancels it—

(A) You return the employee immediately to the performance of safety-sensitive duties;

(B) The employee suffers no adverse personnel or financial consequences as a result; and

(C) You maintain no individually identifiable record that the employee had a confirmed laboratory positive, adulterated, or substituted test result (i.e., you maintain a record of the test only as a negative or cancelled test).

(d) The Administrator of the concerned DOT agency, or his or her designee, may grant a waiver request only if he or she determines that, in the context of your organization, there is a high probability that the procedures you propose will effectively enhance safety and protect the interests of employees in fairness and confidentiality.

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

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

(e) You must not stand employees down in the absence of a waiver, or inconsistent with the terms of your waiver. If you do, you are in violation of this part and DOT agency drug testing regulations, and you are subject to enforcement action by the DOT agency just as you are for other violations of this part and DOT agency rules.

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

a) As an employer who receives a verified positive drug test result, you must immediately remove the employee involved from performing safety-sensitive functions. You must take this action upon receiving the initial report of the verified positive test result. Do not wait to receive the written report or the result of a split specimen test.

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

(c) As an employer who receives an alcohol test result of 0.04 or higher, you must immediately remove the employee involved from performing safety-sensitive functions. If you receive an alcohol test result of 0.02—0.039, you must temporarily remove the employee involved from performing safety-sensitive functions, as provided in applicable DOT agency regulations. Do not wait to receive the written report of the result of the test.

(d) As an employer, when an employee has a verified positive, adulterated, or substituted test result, or has otherwise violated a DOT agency drug and alcohol regulation, you must not return the employee to the performance of safety-sensitive functions until or unless the employee successfully completes the return-to-duty process of Subpart O of this part.

(e) As an employer who receives a drug test result indicating that the employee's specimen was dilute, take action as provided in §40.197.

(f) As an employer who receives a drug test result indicating that the employee's urine specimen test was cancelled because it was invalid and that a second collection must take place under direct observation—

(1) You must immediately direct the employee to provide a new specimen under direct observation.

(2) You must not attach consequences to the finding that the test was invalid other than collecting a new specimen under direct observation.

(3) You must not give any advance notice of this test requirement to the employee.

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

(5) You must ensure that the collector conducts the collection under direct observation.

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

(h) As an employer, you may also be required to take additional actions required by DOT agency regulations (e.g., FAA rules require some positive drug tests to be reported to the Federal Air Surgeon).

(i) As an employer, you must not alter a drug or alcohol test result transmitted to you by an MRO, BAT, or C/TPA.

[65 FR 79526, Dec.19, 2000, as amended at 71 FR 49384, Aug. 23, 2006; 73 FR 35970, June 25, 2008]

§ 40.25 Must an employer check on the drug and alcohol testing record of employees it is intending to use to perform safety-sensitive duties?

(a) Yes, as an employer, you must, after obtaining an employee's written consent, request the information about the employee listed in paragraph (b) of this section. This requirement applies only to employees seeking to begin performing safety-sensitive duties for you for the first time (i.e., a new hire, an employee transfers into a safety-sensitive position). If the employee refuses to provide this written consent, you must not permit the employee to perform safety-sensitive functions.

(b) You must request the information listed in this paragraph (b) from DOT-regulated employers who have employed the employee during any period during the two years before the date of the employee's application or transfer:

(1) Alcohol tests with a result of 0.04 or higher alcohol concentration;

(2) Verified positive drug tests;

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

(4) Other violations of DOT agency drug and alcohol testing regulations; and

(5) With respect to any employee who violated a DOT drug and alcohol regulation, documentation of the employee's successful completion of DOT return-to-duty requirements (including follow-up tests). If the previous employer does not have information about the return-do-duty process (e.g., an employer who did not hire an employee who tested positive on a pre-employment test), you must seek to obtain this information from the employee.

(c) The information obtained from a previous employer includes any drug or alcohol test information obtained from previous employers under this section or other applicable DOT agency regulations.

(d) If feasible, you must obtain and review this information before the employee first performs safety-sensitive functions. If this is not feasible, you must obtain and review the information as soon as possible. However, you must not permit the employee to perform safety-sensitive functions after 30 days from the date

on which the employee first performed safety-sensitive functions, unless you have obtained or made and documented a good faith effort to obtain this information.

(e) If you obtain information that the employee has violated a DOT agency drug and alcohol regulation, you must not use the employee to perform safety-sensitive functions unless you also obtain information that the employee has subsequently complied with the return-to-duty requirements of Subpart O of this part and DOT agency drug and alcohol regulations.

(f) You must provide to each of the employers from whom you request information under paragraph (b) of this section written consent for the release of the information cited in paragraph (a) of this section.

(g) The release of information under this section must be in any written form (e.g., fax, e-mail, letter) that ensures confidentiality. As the previous employer, you must maintain a written record of the information released, including the date, the party to whom it was released, and a summary of the information provided.

(h) If you are an employer from whom information is requested under paragraph (b) of this section, you must, after reviewing the employee's specific, written consent, immediately release the requested information to the employer making the inquiry.

(i) As the employer requesting the information required under this section, you must maintain a written, confidential record of the information you obtain or of the good faith efforts you made to obtain the information. You must retain this information for three years from the date of the employee's first performance of safety-sensitive duties for you.

(j) As the employer, you must also ask the employee whether he or she has tested positive, or refused to test, on any pre-employment drug or alcohol test administered by an employer to which the employee applied for, but did not obtain, safety-sensitive transportation work covered by DOT agency drug and alcohol testing rules during the past two years. If the employee admits that he or she had a positive test or a refusal to test, you must not use the employee to perform safety-sensitive functions for you, until and unless the employee documents successful completion of the return-to-duty process (see paragraphs (b)(5) and (e) of this section).

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

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

[68 FR 43952, July 25, 2003]

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

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

[66 FR 41950, Aug. 9, 2001]

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

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

§40.3—Definition.

§40.35—Information about DERs that employers must provide collectors.

§40.45—Modifying CCFs, Use of foreign-language CCFs.

§40.47—Use of non-Federal forms for DOT tests or Federal CCFs for non-DOT tests.

§40.67—Requirements for direct observation.

§§40.103–40.105—Blind specimen requirements.

§40. 173—Responsibility to ensure test of split specimen.

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

Subpart C - Urine Collection Personnel

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

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

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

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

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

§ 40.33 What training requirements must a collector meet?

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

(a) Basic information. You must be knowledgeable about this part, the current "DOT Urine Specimen Collection Procedures Guidelines," and DOT agency regulations applicable to the employers for whom you perform collections, and you must keep current on any changes to these materials. The DOT Urine Specimen Collection Procedures Guidelines document is available from ODAPC (Department of Transportation, 1200 New Jersey Avenue, SE, Washington DC, 20590, 202–366–3784, or on the ODAPC web site (*http://www.dot.gov/ost/dapc)*.

(b) Qualification training. You must receive qualification training meeting the requirements of this paragraph. Qualification training must provide instruction on the following subjects:

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

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

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

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

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

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

(2) Another person must monitor and evaluate your performance, in person or by a means that provides real-time observation and interaction between the instructor and trainee, and attest in writing that the mock collections are "error-free." This person must be a qualified collector who has demonstrated necessary knowledge, skills, and abilities by—

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

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

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

(d) Schedule for qualification training and initial proficiency demonstration. The following is the schedule for qualification training and the initial proficiency demonstration you must meet:

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

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

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

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

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

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

(2) Error correction training is required to cover only the subject matter area(s) in which the error that caused the test to be cancelled occurred.

(3) As part of the error correction training, you must demonstrate your proficiency in the collection procedures of this part by completing three consecutive error-free mock collections. The mock collections must include one uneventful scenario and two scenarios related to the area(s) in which your error(s) occurred. The person providing the training must monitor and evaluate your performance and attest in writing that the mock collections were "error-free."

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

[65 FR 79526, Dec 19, 2000; 66 FR 3885, Jan. 17, 2001, as amended at 66 FR 41950, Aug. 9, 2001; 73 FR 33329, June 12, 2008]

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(1) To avoid distraction that could compromise security, you are limited to conducting a collection for only one employee at a time. However, during the time one employee is in the period for drinking fluids in a "shy bladder" situation (see §40.193(b)), you may conduct a collection for another employee.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(3) As an employer, you may add the name of the DOT agency under whose authority the test occurred as part of the employer information.

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

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

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

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

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

(a) No, as an employer, you are prohibited from using the CCF for non-Federal urine collections. You are also prohibited from using non-Federal forms for DOT urine collections. Doing either subjects you to enforcement action under DOT agency regulations.

(b) (1) In the rare case where the collector, either by mistake or as the only means to conduct a test under difficult circumstances (e.g., post-accident or reasonable suspicion test with insufficient time to obtain the CCF), uses a non-Federal form for a DOT collection, the use of a non-Federal form does not present a reason for the laboratory to reject the specimen for testing or for an MRO to cancel the result.

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

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

§ 40.49 What materials are used to collect urine specimens?

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

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

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

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

Subpart E - Urine Specimen Collections

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

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

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

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

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

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

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

(3) You must not collect, by catheterization or other means, urine from an unconscious employee to conduct a drug test under this part. Nor may you catheterize a conscious employee. However, you must inform an employee who normally voids through self-catheterization that the employee is required to provide a specimen in that manner.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(a) Complete Step 1 of the CCF.

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

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

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

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

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

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

possible, inform the DER and collection site supervisor that a collection took place under direct observation and the reason for doing so.

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

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

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

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

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

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

(4) You must discard any excess urine.

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

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

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

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

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

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

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

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

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

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

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

(3) In a case where the employee refuses to provide a specimen under direct observation (see §40.191(a)(4)), you must discard any specimen the employee provided previously during the collection procedure. Then you must notify the DER as soon as practicable.

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

§ 40.67 When and how is a directly observed collection conducted?

(a) As an employer, you must direct an immediate collection under direct observation with no advance notice to the employee, if:

(1) The laboratory reported to the MRO that a specimen is invalid, and the MRO reported to you that there was not an adequate medical explanation for the result;

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

(3) The laboratory reported to the MRO that the specimen was negative-dilute with a creatinine concentration greater than or equal to 2 mg/dL but less than or equal to 5 mg/dL, and the MRO reported the specimen to you as negative-dilute and that a second collection must take place under direct observation (see §40.197(b)(1)).

(b) As an employer, you must direct a collection under direct observation of an employee if the drug test is a return-to-duty test or a follow-up test.

(c) As a collector, you must immediately conduct a collection under direct observation if:

(1) You are directed by the DER to do so (see paragraphs (a) and (b) of this section); or

(2) You observed materials brought to the collection site or the employee's conduct clearly indicates an attempt to tamper with a specimen (see §§40.61(f)(5)(i) and 40.63(e)); or

(3) The temperature on the original specimen was out of range (see §40.65(b)(5)); or (4) The original specimen appeared to have been tampered with (see §40.65(c)(1)).

(d)(1) As the employer, you must explain to the employee the reason for a directly observed collection under paragraph (a) or (b) of this section.

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

(e) As the collector, you must complete a new CCF for the directly observed collection.

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

(2) You must check the "Observed, (Enter Remark)" box and enter the reason (see §40.67(b)) in the "Remarks" line (Step 2).

(f) In a case where two sets of specimens are being sent to the laboratory because of suspected tampering with the specimen at the collection site, enter on the "Remarks" line of the CCF (Step 2) for each specimen a notation to this effect (e.g., collection 1 of 2, or 2 of 2) and the specimen ID number of the other specimen.

(g) As the collector, you must ensure that the observer is the same gender as the employee. You must never permit an opposite gender person to act as the observer. The observer can be a different person from the collector and need not be a qualified collector.

(h) As the collector, if someone else is to observe the collection (e.g., in order to ensure a same gender observer), you must verbally instruct that person to follow procedures at paragraphs (i) and (j) of this section. If you, the collector, are the observer, you too must follow these procedures.

(i) As the observer, you must request the employee to raise his or her shirt, blouse, or dress/skirt, as appropriate, above the waist; and lower clothing and underpants to show you, by turning around, that they do not have a prosthetic device. After you have determined that the employee does not have such a device, you may permit the employee to return clothing to its proper position for observed urination.

(j) As the observer, you must watch the employee urinate into the collection container. Specifically, you are to watch the urine go from the employee's body into the collection container.

(k) As the observer but not the collector, you must not take the collection container from the employee, but you must observe the specimen as the employee takes it to the collector.

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

(m) As the employee, if you decline to allow a directly observed collection required or permitted under this section to occur, this is a refusal to test.

(n) As the collector, when you learn that a directly observed collection should have been collected but was not, you must inform the employer that it must direct the employee to have an immediate recollection under direct observation.

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

§ 40.69 How is a monitored collection conducted?

(a) As the collector, you must secure the room being used for the monitored collection so that no one except the employee and the monitor can enter it until after the collection has been completed.

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

(c) As the collector, if someone else is to monitor the collection (e.g., in order to ensure a same-gender monitor), you must verbally instruct that person to follow the procedures of paragraphs (d) and (e) of this section. If you, the collector, are the monitor, you must follow these procedures.

(d) As the monitor, you must not watch the employee urinate into the collection container. If you hear sounds or make other observations indicating an attempt to tamper with a specimen, there must be an additional collection under direct observation (see §§40.63(e), 40.65(c), and 40.67(b)).

(e) As the monitor, you must ensure that the employee takes the collection container directly to the collector as soon as the employee has exited the enclosure.

(f) As the collector, when someone else has acted as the monitor, you must note that person's name in the "Remarks" line of the CCF (Step 2).

(g) As the employee being tested, if you decline to permit a collection authorized under this section to be monitored, it is a refusal to test.

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

§ 40.71 How does the collector prepare the specimens?

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

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

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

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

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

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

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

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

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

(8) You must discard any urine left over in the collection container after both specimen bottles have been appropriately filled and sealed. There is one exception to this requirement: you may use excess urine to conduct clinical tests (e.g., protein, glucose) if the collection was conducted in conjunction with a physical examination required by a DOT agency regulation. Neither you nor anyone else may conduct further testing

(such as adulteration testing) on this excess urine and the employee has no legal right to demand that the excess urine be turned over to the employee.
[65 FR 79526, Dec. 19, 2000, as amended at 66 FR 41951, Aug. 9, 2001]

§ 40.73 How is the collection process completed?

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

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

(2) Complete the chain of custody on the CCF (Step 4) by printing your name (note: you may pre-print your name), recording the time and date of the collection, signing the statement, and entering the name of the delivery service transferring the specimen to the laboratory,

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

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

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

(6) Secure both pouches of the plastic bag.

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

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

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

(ii) Seal the container as appropriate.

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

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

(b) As a collector or collection site, you must ensure that each specimen you collect is shipped to a laboratory as quickly as possible, but in any case within 24 hours or during the next business day.
[65 FR 79526, Dec. 19, 2000, as amended at 71 FR 49384, Aug. 23, 2006]

Subpart F - Drug Testing Laboratories

§ 40.81 What laboratories may be used for DOT drug testing?

(a) As a drug testing laboratory located in the U.S., you are permitted to participate in DOT drug testing only if you are certified by HHS under the National Laboratory Certification Program (NLCP) for all testing required under this part.

(b) As a drug testing laboratory located in Canada or Mexico which is not certified by HHS under the NLCP, you are permitted to participate in DOT drug testing only if:

(1) The DOT, based on a written recommendation from HHS, has approved your laboratory as meeting HHS laboratory certification standards or deemed your laboratory fully equivalent to a laboratory meeting HHS laboratory certification standards for all testing required under this part; or

(2) The DOT, based on a written recommendation from HHS, has recognized a Canadian or Mexican certifying organization as having equivalent laboratory certification standards and procedures to those of HHS, and the Canadian or Mexican certifying organization has certified your laboratory under those equivalent standards and procedures.

(c) As a laboratory participating in the DOT drug testing program, you must comply with the requirements of this part. You must also comply with all applicable requirements of HHS in testing DOT specimens, whether or not the HHS requirements are explicitly stated in this part.

(d) If DOT determines that you are in noncompliance with this part, you could be subject to PIE proceedings under Subpart R of this part. If the Department issues a PIE with respect to you, you are ineligible to participate in the DOT drug testing program even if you continue to meet the requirements of paragraph (a) or (b) of this section.

§ 40.83 How do laboratories process incoming specimens?

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

(a) You are authorized to receive only the laboratory copy of the CCF. You are not authorized to receive other copies of the CCF nor any copies of the alcohol testing form.

(b) You must comply with applicable provisions of the HHS Guidelines concerning accessioning and processing urine drug specimens.

(c) You must inspect each specimen and CCF for the following "fatal flaws:"

(1) The specimen ID numbers on the specimen bottle and the CCF do not match;

(2) The specimen bottle seal is broken or shows evidence of tampering, unless a split specimen can be redesignated (see paragraph (h) of this section);

(3) The collector's printed name and signature are omitted from the CCF; and

(4) There is an insufficient amount of urine in the primary bottle for analysis, unless the specimens can be redesignated (see paragraph (h) of this section).

(d) When you find a specimen meeting the criteria of paragraph (c) of this section, you must document your findings and stop the testing process. Report the result in accordance with §40.97(a)(3) .

(e) You must inspect each CCF for the presence of the collector's signature on the certification statement in Step 4 of the CCF. Upon finding that the signature is omitted, document the flaw and continue the testing process.

(1) In such a case, you must retain the specimen for a minimum of 5 business days from the date on which you initiated action to correct the flaw.

(2) You must then attempt to correct the flaw by following the procedures of §40.205(b)(1).

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

(f) If you determine that the specimen temperature was not checked and the "Remarks" line did not contain an entry regarding the temperature being outside of range, you must then attempt to correct the problem by following the procedures of §40.208.

(1) In such a case, you must continue your efforts to correct the problem for five business days, before you report the result.

(2) When you have obtained the correction, or five business days have elapsed, report the result in accordance with §40.97(a).

(g) If you determine that a CCF that fails to meet the requirements of §40.45(a) (e.g., a non-Federal form or an expired Federal form was used for the collection), you must attempt to correct the use of the improper form by following the procedures of §40.205(b)(2).

(1) In such a case, you must retain the specimen for a minimum of 5 business days from the date on which you initiated action to correct the problem.

(2) If the problem(s) is not corrected, you must reject the test and report the result in accordance with §40.97(a)(3).

(h) If the CCF is marked indicating that a split specimen collection was collected and if the split specimen does not accompany the primary, has leaked, or is otherwise unavailable for testing, you must still test the primary specimen and follow appropriate procedures outlined in §40.175(b) regarding the unavailability of the split specimen for testing.

(1) The primary specimen and the split specimen can be redesignated (i.e., Bottle B is redesignated as Bottle A, and vice-versa) if:

(i) The primary specimen appears to have leaked out of its sealed bottle and the laboratory believes a sufficient amount of urine exists in the split specimen to conduct all appropriate primary laboratory testing; or

(ii) The primary specimen is labeled as Bottle B, and the split specimen as Bottle A; or

(iii) The laboratory opens the split specimen instead of the primary specimen, the primary specimen remains sealed, and the laboratory believes a sufficient amount of urine exists in the split specimen to conduct all appropriate primary laboratory testing; or

(iv) The primary specimen seal is broken but the split specimen remains sealed and the laboratory believes a sufficient amount of urine exists in the split specimen to conduct all appropriate primary laboratory testing.

(2) In situations outlined in paragraph (g)(1) of this section, the laboratory shall mark through the "A" and write "B," then initial and date the change. A corresponding change shall be made to the other bottle by marking through the "B" and writing "A," and initialing and dating the change.

(i) A notation shall be made on Copy 1 of the CCF (Step 5a) and on any laboratory internal chain of custody documents, as appropriate, for any fatal or correctable flaw.

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

§ 40.85 What drugs do laboratories test for?

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

(a) Marijuana metabolites.

(b) Cocaine metabolites.

(c) Amphetamines.

(d) Opiate metabolites.

(e) Phencyclidine (PCP).

§ 40.87 What are the cutoff concentrations for initial and confirmation tests?

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

Type of Drug or Metabolite	Initial Test	Confirmation Test
(1) Marijuana metabolites (i) Delta-9-tetrahydrocannabinol-9-carboxylic acid (THC)	50	15
(2) Cocaine metabolites (Benzoylecgonine)	300	150
(3) Phencyclidine (PCP)	25	25
(4) Amphetamines (i) Amphetamine (ii) Methamphetamine	1000	500 500 (Specimen must also contain amphetamine at a concentration of greater than or equal to 200 ng/mL

(5) Opiate metabolites	2000	
(i) Codeine		2000
(ii) Morphine		2000
(iii) 6acetylmorphine		10 Test for 6-AM in the specimen. Conduct this test only when specimen contains morphine at a concentration greater than or equal to 2000 ng/mL.

(b) On an initial drug test, you must report a result below the cutoff concentration as negative. If the result is at or above the cutoff concentration, you must conduct a confirmation test.

(c) On a confirmation drug test, you must report a result below the cutoff concentration as negative and a result at or above the cutoff concentration as confirmed positive.

(d) You must report quantitative values for morphine or codeine at 15,000 ng/mL or above.

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

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

(b) As a laboratory, you must conduct validity testing.

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

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

As a laboratory, when you conduct validity testing under §40.89, you must conduct it in accordance with the requirements of this section.

(a) You must determine the creatinine concentration on each primary specimen. You must also determine its specific gravity if you find the creatinine concentration to be less than 20 mg/dL.

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

(c) You must perform one or more validity tests for oxidizing adulterants on each primary specimen.

(d) You must perform additional validity tests on the primary specimen when the following conditions are observed:

(1) Abnormal physical characteristics;

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

(3) Possible unidentified interfering substance or adulterant.

(e) If you determine that the specimen is invalid and HHS guidelines direct you to contact the MRO, you 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.

[65 FR 79526, Dec. 19, 2000, as amended at 69 FR 64867, Nov.9, 2004]

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

(a) As a laboratory you must consider the primary specimen to be dilute when:

(1) The creatinine concentration is greater than or equal to 2mg/dL but less than 20 mg/dL, and

(2) The specific gravity is greater than 1.0010 but less than 1.0030 on a single aliquot.

(b) As a laboratory you must consider the primary specimen to be substituted when the creatinine concentration is less than 2 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.
[65 FR 79526, Dec. 19, 2000, as amended at 69 FR 64867, Nov.9, 2004]

§ 40.95 What are the adulterant cutoff concentrations for initial and confirmation tests?

(a) As a laboratory, you must use the cutoff concentrations for the initial and confirmation adulterant testing as required by the HHS Mandatory Guidelines and you must use two separate aliquots – one for the initial test and another for the confirmation test.

(b) As a laboratory, you must report results at or above the cutoffs (or for pH, at or above or below the values, as appropriate) as adulterated and provide the numerical value that supports the adulterated result.
[65 FR 79526, Dec. 19, 2000, as amended at 73 FR 35970, June 25, 2008]

§ 40.96 What criteria do laboratories use to establish that a specimen is invalid?

(a) As a laboratory, you must use the invalid test result criteria for the initial and confirmation testing as required by the HHS Mandatory Guidelines and you must use two separate aliquots – one for the initial test and another for the confirmation test.

(b) As a laboratory, for a specimen having an invalid result for one of the reasons outlined in the HHS Mandatory Guidelines, you must contact the MRO to discuss whether sending the specimen to another HHS certified laboratory for testing would be useful in being able to report a positive or adulterated result.

(c) As a laboratory, you must report invalid results in accordance with the invalid test result criteria as required by the HHS Guidelines and provide the numerical value that support the invalid result. For pH, report at or above or below the values, as appropriate.

(d) As a laboratory, you must report the reason a test result is invalid.
[73 FR 35970, June 25, 2008]

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

(a) As a laboratory, you must report the results for each primary specimen. The result of a primary specimen will fall into one of the following three categories. However, as a laboratory, you must report the actual results (and not the categories):

(1) Category 1: Negative Results. As a laboratory, when you find a specimen to be negative, you must report the test result as being one of the following, as appropriate:

(i) Negative, or

(ii) Negative-dilute, with numerical values for creatinine and specific gravity.

(2) Category 2: Non-negative Results. As a laboratory, when you find a specimen to be non-negative, you must report the test result as being one or more of the following, as appropriate:

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

(ii) Positive-dilute, with drug(s)/ metabolite(s) noted, with numerical values for creatinine and specific gravity;

(iii) Adulterated, with adulterant(s) noted, with confirmatory test values (when applicable), and with remarks(s);

(iv) Substituted, with confirmatory test values for creatinine and specific gravity; or

(v) Invalid result, with remark(s). Laboratories will report actual values for pH results.

(3) Category 3: Rejected for Testing. As a laboratory, when you reject a specimen for testing, you must report the result as being Rejected for Testing, with remark(s).

(b) As a laboratory, you must report laboratory results directly, and only, to the MRO at his or her place of business. You must not report results to or through the DER or a service agent (e.g., C/TPA).

(1) Negative results: You must fax, courier, mail, or electronically transmit a legible image or copy of the fully-completed Copy 1 of the CCF which has been signed by the certifying scientist, or you may provide the laboratory results report electronically (i.e., computer data file).

(i) If you elect to provide the laboratory results report, you must include the following elements, as a minimum, in the report format:

(A) Laboratory name and address;

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

(C) Medical review officer's name;

(D) Specimen I.D. number;

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

(F) Reason for test, if provided;

(G) Collector's name and telephone number;

(H) Date of the collection;

(I) Date received at the laboratory;

(J) Date certifying scientist released the results;

(K) Certifying scientist's name;

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

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

(ii) You may release the laboratory results report only after review and approval by the certifying scientist. It must reflect the same test result information as contained on the CCF signed by the certifying scientist. The information contained in the laboratory results report may not contain information that does not appear on the CCF.

(iii) The results report may be transmitted through any means that ensures accuracy and confidentiality. You, as the laboratory, together with the MRO, must ensure that the information is adequately protected from unauthorized access or release, both during transmission and in storage.

(2) Non-negative and Rejected for Testing results: You must fax, courier, mail, or electronically transmit a legible image or copy of the fully-completed Copy 1 of the CCF that has been signed by the certifying scientist. In addition, you may provide the electronic laboratory results report following the format and procedures set forth in paragraphs (b)(1)(i) and (ii) of this section.

(c) In transmitting laboratory results to the MRO, you, as the laboratory, together with the MRO, must ensure that the information is adequately protected from unauthorized access or release, both during transmission and in storage. If the results are provided by fax, the fax connection must have a fixed telephone number accessible only to authorized individuals.

(d) You must transmit test results to the MRO in a timely manner, preferably the same day that review by the certifying scientist is completed.

(e)(1) You must provide quantitative values for confirmed positive drug test results to the MRO when the MRO requests you to do so in writing. The MRO's request may be either a general request covering all such results you send to the MRO or a specific case-by-case request.

(2) You must provide numerical values that support the adulterated (when applicable) or substituted result, without a request from the MRO.

(3) You must also provide the MRO numerical values for creatinine and specific gravity for the negative-dilute test result, without a request from the MRO.

(f) You must provide quantitative values for confirmed opiate results for morphine or codeine at 15,000 ng/mL or above, even if the MRO has not requested quantitative values for the test result.

[65 FR 79526, Dec. 19, 2000, as amended at 66 FR 41951, Aug. 9, 2001; 68 FR 31626, May 28, 2003; 69 FR 64867, Nov.9, 2004; 73 FR 35970, June 25, 2008]

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(1) All negative, positive, adulterated, and substituted blind specimens you submit must be certified by the supplier and must have supplier-provided expiration dates.

(2) Negative specimens must be certified by immunoassay and GC/MS to contain no drugs.

(3) Drug positive blind specimens must be certified by immunoassay and GC/MS to contain a drug(s)/ metabolite(s) between 1.5 and 2 times the initial drug test cutoff concentration.

(4) Adulterated blind specimens must be certified to be adulterated with a specific adulterant using appropriate confirmatory validity test(s).

(5) Substituted blind specimens must be certified for creatinine concentration and specific gravity to satisfy the criteria for a substituted specimen using confirmatory creatinine and specific gravity tests, respectively.

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

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

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

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

[65 FR 79526, Dec. 19, 2000, as amended at 73 FR 35971, June 25, 2008]

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

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

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

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

[65 FR 79526, Dec. 19, 2000, as amended at 73 FR 35971, June 25, 2008]

§ 40.107 Who may inspect laboratories?

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

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

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

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

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

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

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

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

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

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

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

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

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

(d) As a laboratory, you must transmit an aggregate statistical summary of the data listed in Appendix C to this part to DOT on a semi-annual basis. The summary must be sent by January 31 of each year for July 1 through December 31 of the prior year; it must be sent by July 31 of each year for January 1 through June 30 of the current year.

[65 FR 79526, Dec. 19, 2000, as amended at 73 FR 35971, June 25, 2008]

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

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

§40.3—Definition.

§40.13—Prohibition on making specimens available for other purposes.

§40.31—Conflicts of interest concerning collectors.

§40.47—Laboratory rejections of test for improper form.

§40.125—Conflicts of interest concerning MROs.

§40.175—Role of first laboratory in split specimen tests.

§40.177—Role of second laboratory in split specimen tests (drugs).

§40.179—Role of second laboratory in split specimen tests (adulterants).

§40.181—Role of second laboratory in split specimen tests (substitution).

§§40.183–40.185—Transmission of split specimen test results to MRO.

§§40.201–40.205—Role in correcting errors.

§40.329—Release of information to employees.

§40.331—Limits on release of information.

§40.355—Role with respect to other service agents.

Subpart G - Medical Review Officers and the Verification Process

§ 40.121 Who is qualified to act as an MRO?

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

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

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

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

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

(3) You must be knowledgeable about this part, the DOT MRO Guidelines, and the DOT agency regulations applicable to the employers for whom you evaluate drug test results, and you must keep current on any changes to these materials. The DOT MRO Guidelines document is available from ODAPC (Department of Transportation, 1200 New Jersey Avenue, SE, Washington DC, 20590, 202–366–3784, or on the ODAPC web site
(*http://www.dot.gov/ost/dapc*).

(c) Qualification training. You must receive qualification training meeting the requirements of this paragraph (c).

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

(i) Collection procedures for urine specimens;

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

(iii) Interpretation of drug and validity tests results;

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

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

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

(2) Following your completion of qualification training under paragraph (c)(1) of this section, you must satisfactorily complete an examination administered by a nationally-recognized MRO certification board or subspecialty board for medical practitioners in the field of medical review of DOT-mandated drug tests. The examination must comprehensively cover all the elements of qualification training listed in paragraph (c)(1) of this section.

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

(i) If you became an MRO before August 1, 2001, and have already met the qualification training requirement, you do not have to meet it again.

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

(iii) If you become an MRO on or after August 1, 2001, you must meet the qualification training requirement before you begin to perform MRO functions.

(d) Continuing Education. During each three-year period from the date on which you satisfactorily complete the examination under paragraph (c)(2) of this section, you must complete continuing education consisting of at least 12 professional development hours (e.g., Continuing Education Medical Units) relevant to performing MRO functions.

(1) This continuing education must include material concerning new technologies, interpretations, recent guidance, rule changes, and other information about developments in MRO practice, pertaining to the DOT program, since the time you met the qualification training requirements of this section.

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

(3) If you are an MRO who completed the qualification training and examination requirements prior to August 1, 2001, you must complete your first increment of 12 CEU hours before August 1, 2004.

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

[65 FR 79526, Dec. 19, 2000, as amended at 66 FR 41951, Aug. 9, 2001; 73 FR 33329, June 12, 2008]

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

As an MRO, you have the following basic responsibilities:

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

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

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

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

(3) Reporting to and consulting with the ODAPC or a relevant DOT agency when you wish DOT assistance in resolving any program issue. As an employer or service agent, you are prohibited from limiting or attempting to limit the MRO's access to DOT for this purpose and from retaliating in any way against an MRO for discussing drug testing issues with DOT.

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

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

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

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

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

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

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

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

relationships between laboratories and MROs that the Department views as creating a conflict of interest or the appearance of such a conflict, see §40.101(b).

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

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

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

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

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

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

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

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

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

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

(g) Staff under your direct, personal supervision may perform the administrative functions of this section for you, but only you can cancel a test. If you cancel a laboratory-confirmed negative result, check the "Test Cancelled" box (Step 6) on Copy 2 of the CCF, make appropriate annotation in the "Remarks" line, provide your name, and sign, initial or stamp and date the verification statement.

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

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

(3) Your review must, as a minimum, include the CCF, negative laboratory test result, any accompanying corrective documents, and the report sent to the employer. You must correct any errors that you discover. You must take action as necessary to ensure compliance by your staff with this part and document your corrective action. You must attest to the quality assurance review by initialing the CCFs that you review.

(4) You must make these CCFs easily identifiable and retrievable by you for review by DOT agencies. [65 FR 79526, Dec. 19, 2000, as amended at 66 FR 41951, Aug. 9, 2001]

§ 40.129 What are the MRO's functions in reviewing laboratory confirmed non-negative drug test results?

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

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

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

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

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

(5) Verify the test result, consistent with the requirements of §§ 40.135 through 40.145, 40.159, and 40.160, as:

(i) Negative; or

(ii) Cancelled; or

(iii) Positive, and/or refusal to test because of adulteration or substitution.

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

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

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

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

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

(e) Report the result in a confidential manner (see §§40.163–40.167).

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

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

(1) If an employer has a stand-down policy that meets the requirements of §40.21 , you may report to the DER that you have received an employee's laboratory confirmed positive, adulterated, or substituted test result, consistent with the terms of the waiver the employer received. You must not provide any further details about the test result (e.g., the name of the drug involved).

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

[65 FR 79526, Dec. 19, 2000, as amended at 66 FR 41952, Aug. 9, 2001; 73 FR 35971, June 25, 2008]

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

(a) When, as the MRO, you receive a confirmed positive, adulterated, substituted, or invalid test result from the laboratory, you must contact the employee directly (i.e., actually talk to the employee), on a confidential basis, to determine whether the employee wants to discuss the test result. In making this contact, you must explain to the employee that, if he or she declines to discuss the result, you will verify the test as positive or as a refusal to test because of adulteration or substitution, as applicable.

(b) As the MRO, staff under your personal supervision may conduct this initial contact for you.

(1) This staff contact must be limited to scheduling the discussion between you and the employee and explaining the consequences of the employee's declining to speak with you (i.e., that the MRO will verify the

test without input from the employee). If the employee declines to speak with you, the staff person must document the employee's decision, including the date and time.

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

(3) A staff person may advise an employee to have medical information (e.g., prescriptions, information forming the basis of a legitimate medical explanation for a confirmed positive test result) ready to present at the interview with the MRO.

(4) Since you are required to speak personally with the employee, face-to-face or on the phone, your staff must not inquire if the employee wishes to speak with you.

(c) As the MRO, you or your staff must make reasonable efforts to reach the employee at the day and evening telephone numbers listed on the CCF. Reasonable efforts include, as a minimum, three attempts, spaced reasonably over a 24-hour period, to reach the employee at the day and evening telephone numbers listed on the CCF. If you or your staff cannot reach the employee directly after making these efforts, you or your staff must take the following steps:

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

(2) Contact the DER, instructing the DER to contact the employee.

(i) You must simply direct the DER to inform the employee to contact you.

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

(iii) You must document the dates and times of your attempts to contact the DER, and you must document the name of the DER you contacted and the date and time of the contact.

(d) As the DER, you must attempt to contact the employee immediately, using procedures that protect, as much as possible, the confidentiality of the MRO's request that the employee contact the MRO. If you successfully contact the employee (i.e., actually talk to the employee), you must document the date and time of the contact, and inform the MRO. You must inform the employee that he or she should contact the MRO immediately. You must also inform the employee of the consequences of failing to contact the MRO within the next 72 hours (see §40.133(a)(2)).

(1) As the DER, you must not inform anyone else working for the employer that you are seeking to contact the employee on behalf of the MRO.

(2) If, as the DER, you have made all reasonable efforts to contact the employee but failed to do so, you may place the employee on temporary medically unqualified status or medical leave. Reasonable efforts include, as a minimum, three attempts, spaced reasonably over a 24-hour period, to reach the employee at the day and evening telephone numbers listed on the CCF.

(i) As the DER, you must document the dates and times of these efforts.

(ii) If, as the DER, you are unable to contact the employee within this 24-hour period, you must leave a message for the employee by any practicable means (e.g., voice mail, e-mail, letter) to contact the MRO and inform the MRO of the date and time of this attempted contact.

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

§ 40.133 Without interviewing the employee, under what circumstances may the MRO verify a test result as positive, or as a refusal to test because of adulteration or substitution, or as cancelled because the test was invalid?

(a) As the MRO, you normally may verify a confirmed positive test (for any drug or drug metabolite, including opiates), or as a refusal to test because of adulteration or substitution, only after interviewing the

employee as provided in §§40.135–40.145. However, there are three circumstances in which you may verify such a result without an interview:

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

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

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

(b) As the MRO, you may verify an invalid test result as cancelled (with instructions to recollect immediately under direct observation) without interviewing the employee, as provided at § 40.159:

(1) If the employee expressly declines the opportunity to discuss the test with you;

(2) If the DER has successfully made and documented a contact with the employee and instructed the employee to contact you and more than 72 hours have passed since the time the DER contacted the employee; or

(3) If neither you nor the DER, after making and documenting all reasonable efforts, has been able to contact the employee within ten days of the date on which you received the confirmed invalid test result from the laboratory.

(c) As the MRO, after you verify a test result as a positive or as a refusal to test under this section, you must document the date and time and reason, following the instructions in § 40.163. For a cancelled test due to an invalid result under this section, you must follow the instructions in § 40.159(a)(5).

(d) As the MRO, after you have verified a test result under this section and reported the result to the DER, you must allow the employee to present information to you within 60 days of the verification to document that serious illness, injury, or other circumstances unavoidably precluded contact with the MRO and/or DER in the times provided. On the basis of such information, you may reopen the verification, allowing the employee to present information concerning whether there is a legitimate medical explanation of the confirmed test result. [65 FR 79526, Dec. 19, 2000, as amended at 73 FR 35971, June 25, 2008]

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

(a) As the MRO, you must tell the employee that the laboratory has determined that the employee's test result was positive, adulterated, substituted, or invalid, as applicable. You must also tell the employee of the drugs for which his or her specimen tested positive, or the basis for the finding of adulteration or substitution.

(b) You must explain the verification interview process to the employee and inform the employee that your decision will be based on information the employee provides in the interview.

(c) You must explain that, if further medical evaluation is needed for the verification process, the employee must comply with your request for this evaluation and that failure to do so is equivalent of expressly declining to discuss the test result.

(d) As the MRO, you must warn an employee who has a confirmed positive, adulterated, substituted or invalid test that you are required to provide to third parties drug test result information and medical information affecting the performance of safety-sensitive duties that the employee gives you in the verification process without the employee's consent (see §40.327).

(1) You must give this warning to the employee before obtaining any medical information as part of the verification process.

(2) For purposes of this paragraph (d), medical information includes information on medications or other substances affecting the performance of safety-sensitive duties that the employee reports using or medical conditions the employee reports having.

(3) For purposes of this paragraph (d), the persons to whom this information may be provided include the employer, a SAP evaluating the employee as part of the return to duty process (see §40.293(g)), DOT, another Federal safety agency (e.g., the NTSB), or any state safety agency as required by state law.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(i) Recent needle tracks;

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

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

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

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

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

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

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

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

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

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

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

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

§ 40.143 [Reserved]

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

(a) As an MRO, when you receive a laboratory report that a specimen is adulterated or substituted, you must treat that report in the same way you treat the laboratory's report of a confirmed positive test for a drug or drug metabolite.

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

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

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

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

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

(2) To meet this burden in the case of a substituted specimen, the employee must demonstrate that he or she did produce or could have produced urine through physiological means, meeting the creatinine concentration criterion of less than 2 mg/dL and the specific gravity of less than or equal to 1.0010 or greater than or equal to 1.0200 (see §40.93(b)).

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

[65 FR 79526, Dec. 19, 2000, as amended at 68 FR 31626, May 28, 2003; 69 FR 64867, Nov.9, 2004]

§ 40.147 [Reserved]

§ 40.149 May the MRO change a verified drug test result?

(a) As the MRO, you may change a verified test result only in the following situations:

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

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

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

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

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

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

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

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

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

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

[65 FR 79526, Dec. 19, 2000, as amended at 66 FR 41952, Aug. 9, 2001; 73 FR 35971, June 25, 2008]

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

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

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

(b) It is not your function to make decisions about factual disputes between the employee and the collector concerning matters occurring at the collection site that are not reflected on the CCF (e.g., concerning allegations that the collector left the area or left open urine containers where other people could access them).

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(c) When you report a dilute specimen to the DER, you must explain to the DER the employer's obligations and choices under §40.197, 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 2mg/dL but less than or equal to 5mg/dL.

(d) If the employee's recollection under direct observation, in paragraph (c) of this section, results in another negative-dilute, as the MRO, you must:

(1) Review the CCF to ensure that there is documentation that the recollection was directly observed.

(2) If the CCF documentation shows that the recollection was directly observed as required, report this result to the DER as a negative-dilute result.

(3) If CCF documentation indicates that the recollection was not directly observed as required, do not report a result but again explain to the DER that there must be an immediate recollection under direct observation.

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

§ 40.157 [Reserved]

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

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

(1) Discuss the laboratory results with a certifying scientist to determine if the primary specimen should be tested at another HHS certified laboratory. If the laboratory did not contact you as required by §§ 40.91(e) and 40.96(c), you must contact the laboratory.

(2) If you and the laboratory have determined that no further testing is necessary, contact the employee and inform the employee that the specimen was invalid. In contacting the employee, use the procedures set forth in § 40.131.

(3) After explaining the limits of disclosure (see §§ 40.135(d) and 40.327), you must determine if the employee has a medical explanation for the invalid result. You must inquire about the medications the employee may have taken.

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

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

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

(iii) If a negative test result is required and the medical explanation concerns a situation in which the employee has a permanent or long-term medical condition that precludes him or her from providing a valid specimen, as the MRO, you must follow the procedures outlined at § 40.160 for determining if there is clinical evidence that the individual is an illicit drug user.

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

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

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

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

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

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

(d) If the employee admits to using a drug, you must, on the same day, write and sign your own statement of what the employee told you. You must then report that admission to the DER for appropriate action under DOT Agency regulations. This test will be reported as cancelled with the reason noted.

(e) If the employee's recollection (required at paragraph (a)(5) of this section) results in another invalid result for the same reason as reported for the first specimen, as the MRO, you must:

(1) Review the CCF to ensure that there is documentation that the recollection was directly observed.

(2) If the CCF review indicates that the recollection was directly observed as required, document that the employee had another specimen with an invalid result for the same reason.

(3) Follow the recording and reporting procedures at (a)(4)(i) and (ii) of this section.

(4) If a negative result is required (i.e., pre-employment, return-to-duty, or follow-up tests), follow the procedures at § 40.160 for determining if there is clinical evidence that the individual is an illicit drug user.

(5) If the recollection was not directly observed as required, do not report a result but again explain to the DER that there must be an immediate recollection under direct observation.

(f) If the employee's recollection (required at paragraph (a)(5) of this section) results in another invalid result for a different reason than that reported for the first specimen, as the MRO, you must:

(1) Review the CCF to ensure that there is documentation that the recollection was directly observed.

(2) If the CCF review indicates that the recollection was directly observed as required, document that the employee had another specimen with an invalid result for a different reason.

(3) As the MRO, you should not contact the employee to discuss the result, but rather direct the DER to conduct an immediate recollection under direct observation without prior notification to the employee.

(4) If the CCF documentation indicates that the recollection was not directly observed as required, do not report a result but again explain to the DER that there must be an immediate recollection under direct observation.

(g) If, as the MRO, you receive a laboratory invalid result in conjunction with a positive, adulterated, and/or substituted result and you verify any of those results as being a positive and/or refusal to test, you do not report the invalid result unless the split specimen fails to reconfirm the result(s) of the primary specimen.
[65 FR 79526, Dec. 19, 2000 as amended at 73 FR 35972, June 25, 2008]

§ 40.160 What does the MRO do when a valid test result cannot be produced and a negative result is required?

(a) If a valid test result cannot be produced and a negative result is required, (under § 40.159 (a)(5)(iii) and (e)(4)), as the MRO, you must determine if there is clinical evidence that the individual is currently an illicit drug user. You must make this determination by personally conducting, or causing to be conducted, a medical evaluation. In addition, if appropriate, you may also consult with the employee's physician to gather information you need to reach this determination.

(b) If you do not personally conduct the medical evaluation, as the MRO, you must ensure that one is conducted by a licensed physician acceptable to you.

(c) For purposes of this section, the MRO or the physician conducting the evaluation may conduct an alternative test (e.g., blood) as part of the medically appropriate procedures in determining clinical evidence of drug use.

(d) If the medical evaluation reveals no clinical evidence of drug use, as the MRO, you must report this to the employer as a negative test result with written notations regarding the medical examination. The report must also state why the medical examination was required (i.e., either the basis for the determination that a permanent or long-term medical condition exists or because the recollection under direct observation resulted in another invalid result for the same reason, as appropriate) and for the determination that no signs and symptoms of drug use exist.

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

(2) Sign and date the CCF.

(e) If the medical evaluation reveals clinical evidence of drug use, as the MRO, you must report the result to the employer as a cancelled test with written notations regarding the results of the medical examination. The report must also state why the medical examination was required (i.e., either the basis for the determination that a permanent or long-term medical condition exists or because the recollection under direct observation resulted in another invalid result for the same reason, as appropriate) 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 purpose of an actual negative test result (i.e., the employer is not authorized to allow the employee to begin or resume performing safety-sensitive functions, because a negative test result is needed for that purpose).
[73 FR 35972, June 25, 2008]

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

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

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

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

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

§ 40.162 What must MROs do with multiple verified results for the same testing event?

(a) If the testing event is one in which there was one specimen collection with multiple verified non-negative results, as the MRO, you must report them all to the DER. For example, if you verified the specimen

as being positive for marijuana and cocaine and as being a refusal to test because the specimen was also adulterated, as the MRO, you should report the positives and the refusal to the DER.

(b) If the testing event was one in which two separate specimen collections (e.g., a specimen out of temperature range and the subsequent observed collection) were sent to the laboratory, as the MRO, you must:

(1) If both specimens were verified negative, report the result as negative.

(2) If either of the specimens was verified negative and the other was verified as one or more non-negative(s), report the non-negative result(s) only. For example, if you verified one specimen as negative and the other as a refusal to test because the second specimen was substituted, as the MRO you should report only the refusal to the DER.

(i) If the first specimen is reported as negative, but the result of the second specimen has not been reported by the laboratory, as the MRO, you should hold – not report – the result of the first specimen until the result of the second specimen is received.

(ii) If the first specimen is reported as non-negative, as the MRO, you should report the result immediately and not wait to receive the result of the second specimen.

(3) If both specimens were verified non-negative, report all of the non-negative results. For example, if you verified one specimen as positive and the other as a refusal to test because the specimen was adulterated, as the MRO, you should report the positive and the refusal results to the DER.

(c) As an exception to paragraphs (a) and (b) of this section, as the MRO, you must follow procedures at § 40.159(f) when any verified non-negative result is also invalid.

[73 FR 35972, June 25, 2008]

§ 40.163 How does the MRO report drug test results?

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

(b) You may use a signed or stamped and dated legible photocopy of Copy 2 of the CCF to report test results.

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

(1) Full name, as indicated on the CCF, of the employee tested;

(2) Specimen ID number from the CCF and the donor SSN or employee ID number;

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

(4) Date of the collection;

(5) Date you received Copy 2 of the CCF;

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

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

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

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

(d) As an exception to the reporting requirements of paragraph (b) and (c) of this section, the MRO may report negative results using an electronic data file.

(1) If you report negatives using an electronic data file, the report must contain, as a minimum, the information specified in paragraph (c) of this section, as applicable for negative test results.

(2) In addition, the report must contain your name, address, and phone number, the name of any person other than you reporting the results, and the date the electronic results report is released.

(e) You must retain a signed or stamped and dated copy of Copy 2 of the CCF in your records. If you do not use Copy 2 for reporting results, you must maintain a copy of the signed or stamped and dated letter in addition to the signed or stamped and dated Copy 2. If you use the electronic data file to report negatives, you must maintain a retrievable copy of that report in a format suitable for inspection and auditing by a DOT representative.

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

(g) You must not provide quantitative values to the DER or C/TPA for drug or validity test results. However, you must provide the test information in your possession to a SAP who consults with you (see §40.293(g)).

[66 FR 41952, Aug. 9, 2001]

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

(a) As the MRO, you must report all drug test results to the DER, except in the circumstances provided for in §40.345.

(b) If the employer elects to receive reports of results through a C/TPA, acting as an intermediary as provided in §40.345, you must report the results through the designated C/TPA.

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

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

(a) You must report the results in a confidential manner.

(b) You must transmit to the DER on the same day the MRO verifies the result or the next business day all verified positive test results, results requiring an immediate collection under direct observation, adulterated or substituted specimen results, and other refusals to test.

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

(2) You are responsible for identifying yourself to the DER, and the DER must have a means to confirm your identification.

(3) The MRO's report that you transmit to the employer must contain all of the information required by §40.163.

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

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

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

(d) In transmitting test results, you or the C/TPA and the employer must ensure the security of the transmission and limit access to any transmission, storage, or retrieval systems.

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

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

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

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

§40.3—Definition.

§§40.47–40.49—Correction of form and kit errors.

§40.67—Role in direct observation and other atypical test situations.

§40.83—Laboratory handling of fatal and correctable flaws.

§40.97—Laboratory handling of test results and quantitative values.

§40.99—Authorization of longer laboratory retention of specimens.

§40.101—Relationship with laboratories; avoidance of conflicts of interest.

§40.105—Notification of discrepancies in blind specimen results.

§40.171—Request for test of split specimen.
§40.187—Action concerning split specimen test results.
§40.193—Role in "shy bladder" situations.
§40.195—Role in cancelling tests.
§§40.199–40.203—Documenting errors in tests.
§40.327—Confidentiality and release of information.
§40.347—Transfer of records.
§40.353—Relationships with service agents.

Subpart H - Split Specimen Tests

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

(a) As an employee, when the MRO has notified you that you have a verified positive drug test and/or refusal to test because of adulteration or substitution, you have 72 hours from the time of notification to request a test of the split specimen. The request may be verbal or in writing. If you make this request to the MRO within 72 hours, you trigger the requirements of this section for a test of the split specimen. There is no split specimen testing for an invalid result.

(b)(1) If, as an employee, you have not requested a test of the split specimen within 72 hours, you may present to the MRO information documenting that serious injury, illness, lack of actual notice of the verified test result, inability to contact the MRO (e.g., there was no one in the MRO's office and the answering machine was not working), or other circumstances unavoidably prevented you from making a timely request.

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

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

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

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

(a) As the employer, you are responsible for making sure (e.g., by establishing appropriate accounts with laboratories for testing split specimens) that the MRO, first laboratory, and second laboratory perform the functions noted in §§40.175–40.185 in a timely manner, once the employee has made a timely request for a test of the split specimen.

(b) As the employer, you must not condition your compliance with these requirements on the employee's direct payment to the MRO or laboratory or the employee's agreement to reimburse you for the costs of testing. For example, if you ask the employee to pay for some or all of the cost of testing the split specimen, and the employee is unwilling or unable to do so, you must ensure that the test takes place in a timely manner, even though this means that you pay for it.

(c) As the employer, you may seek payment or reimbursement of all or part of the cost of the split specimen from the employee (e.g., through your written company policy or a collective bargaining agreement). This part takes no position on who ultimately pays the cost of the test, so long as the employer ensures that the testing is conducted as required and the results released appropriately.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(d) In addition, if the test fails to reconfirm the presence of the drug(s)/drug metabolite(s) reported in the primary specimen, you may send the specimen or an aliquot of it for testing at another HHS-certified laboratory that has the capability to conduct another reconfirmation test.

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

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

(a) As the laboratory testing the split specimen, you must test the split specimen for the adulterant detected in the primary specimen, using the confirmatory test for the adulterant and using criteria in § 40.95 and confirmatory cutoff levels required by the HHS Mandatory Guidelines.

(b) In addition, if the test fails to reconfirm the adulterant result reported in the primary specimen, you may send the specimen or an aliquot of it for testing at another HHS-certified laboratory that has the capability to conduct another reconfirmation test.

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

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

As the laboratory testing the split specimen, you must test the split specimen using the confirmatory tests for creatinine and specific gravity, and using criteria set forth in § 40.93(b).

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

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

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

CCF, as appropriate, and by providing clarifying remarks using current HHS Mandatory Guidelines requirements.

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

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

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

(a) As the laboratory testing the split specimen, you must report laboratory results directly, and only, to the MRO at his or her place of business. You must not report results to or through the DER or another service agent (e.g., a C/TPA).

(b) You must fax, courier, mail, or electronically transmit a legible image or copy of the fully-completed Copy 1 of the CCF, which has been signed by the certifying scientist.

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

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

As the MRO, the split specimen laboratory results you receive will fall into five categories. You must take the following action, as appropriate, when a laboratory reports split specimen results to you.

(a) Category 1: The laboratory reconfirmed one or more of the primary specimen results. As the MRO, you must report to the DER and the employee the result(s) that was/were reconfirmed.

(1) In the case of a reconfirmed positive test(s) for drug(s) or drug metabolite(s), the positive is the final result.

(2) In the case of a reconfirmed adulterated or substituted result, the refusal to test is the final result.

(3) In the case of a combination positive and refusal to test results, the final result is both positive and refusal to test.

(b) Category 2: The laboratory failed to reconfirm all of the primary specimen results because, as appropriate, drug(s)/drug metabolite(s) were not detected; adulteration criteria were not met; and/or substitution criteria were not met. As the MRO, you must report to the DER and the employee that the test must be cancelled.

(1) As the MRO, you must inform ODAPC of the failure to reconfirm using the format in Appendix D to this part.

(2) In a case where the split failed to reconfirm because the substitution criteria were not met and the split specimen creatinine concentration was equal to or greater than 2mg/dL but less than or equal to 5mg/dL, as the MRO, you must, in addition to step in (b)(1) of this paragraph, direct the DER to ensure the immediate collection of another specimen from the employee under direct observation, with no notice given to the employee of this collection requirement until immediately before the collection.

(3) In a case where the split failed to reconfirm and the primary specimen's result was also invalid, 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.

(c) Category 3: The laboratory failed to reconfirm all of the primary specimen results, and also reported that the split specimen was invalid, adulterated, and/or substituted.

(1) In the case where the laboratory failed to reconfirm all of the primary specimen results and the split was reported as invalid, as the MRO, you must:

(i) Report to the DER and the employee that the test must be cancelled and the reason for the cancellation.

(ii) 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.

(iii) Inform ODAPC of the failure to reconfirm using the format in Appendix D to this part.

(2) In the case where the laboratory failed to reconfirm any of the primary specimen results, and the split was reported as adulterated and/or substituted, as the MRO, you must:

(i) Contact the employee and inform the employee that the laboratory has determined that his or her split specimen is adulterated and/or substituted, as appropriate.

(ii) Follow the procedures of § 40.145 to determine if there is a legitimate medical explanation for the laboratory finding of adulteration and/or substitution, as appropriate.

(iii) If you determine that there is a legitimate medical explanation for the adulterated and/or substituted test result, report to the DER and the employee that the test must be cancelled; and inform ODAPC of the failure to reconfirm using the format in Appendix D to this part.

(iv) If you determine that there is not a legitimate medical explanation for the adulterated and/or substituted test result, you must take the following steps:

(A) Report the test to the DER and the employee as a verified refusal to test. Inform the employee that he or she has 72 hours to request a test of the primary specimen to determine if the adulterant found in the split specimen is also present in the primary specimen and/or to determine if the primary specimen meets appropriate substitution criteria.

(B) Except when the request is for a test of the primary specimen and is being made to the laboratory that tested the primary specimen, follow the procedures of §§ 40.153, 40.171, 40.173, 40.179, 40.181, and 40.185, as appropriate.

(C) As the laboratory that tests the primary specimen to reconfirm the presence of the adulterant found in the split specimen and/or to determine that the primary specimen meets appropriate substitution criteria, report your result to the MRO on a photocopy (faxed, mailed, scanned, couriered) of Copy 1 of the CCF.

(D) If the test of the primary specimen reconfirms the adulteration and/or substitution finding of the split specimen, as the MRO you must report the result as a refusal to test as provided in paragraph (a)(2) of this section.

(E) If the test of the primary specimen fails to reconfirm the adulteration and/or substitution finding of the split specimen, as the MRO you must cancel the test, following procedures in paragraph (b) of this section.

(d) Category 4: The laboratory failed to reconfirm one or more but not all of the primary specimen results, and also reported that the split specimen was invalid, adulterated, and/or substituted. As the MRO, in the case where the laboratory reconfirmed one or more of the primary specimen result(s), you must follow procedures in paragraph (a) of this section and:

(1) Report that the split was also reported as being invalid, adulterated, and/or substituted (as appropriate).

(2) Inform the DER to take action only on the reconfirmed result(s).

(e) Category 5: The split specimen was not available for testing or there was no split laboratory available to test the specimen. As the MRO, you must:

(1) Report to the DER and the employee that the test must be cancelled and the reason for the cancellation;

(2) Direct the DER to ensure the immediate recollection 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; and

(3) Notify ODAPC of the failure to reconfirm using the format in Appendix D to this part.

(f) For all split specimen results, as the MRO you must:

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

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

[65 FR 79526, Dec. 19, 2000, as amended at 66 FR 41953, Aug. 9, 2001; 68 FR 31626, May 28, 2003; 73 FR 35973, June 25, 2008]

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

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

§40.3—Definition.

§40.65—Quantity of split specimen.

§40.67—Directly observed test when split specimen is unavailable.

§§40.71–40.73—Collection process for split specimens.

§40.83—Laboratory accessioning of split specimens.

§40.99—Laboratory retention of split specimens.

§40.103—Blind split specimens.

§40.153—MRO notice to employees on tests of split specimen.

§§40.193 and 40.201—MRO actions on insufficient or unavailable split specimens.

Appendix D to Part 40—Report format for split specimen failure to reconfirm.

Subpart I—Problems in Drug Tests

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

(a) As an employee, you have refused to take a drug test if you:

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

(2) Fail to remain at the testing site until the testing process is complete; Provided, That an employee who leaves the testing site before the testing process commences (see §40.63 (c)) for a pre-employment test is not deemed to have refused to test;

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

(4) In the case of a directly observed or monitored collection in a drug test, fail to permit the observation or monitoring of your provision of a specimen (see §§40.67(l) and 40.69(g));

(5) Fail to provide a sufficient amount of urine when directed, and it has been determined, through a required medical evaluation, that there was no adequate medical explanation for the failure (see §40.193(d)(2));

(6) Fail or decline to take an additional drug test the employer or collector has directed you to take (see, for instance, §40.197(b));

(7) Fail to undergo a medical examination or evaluation, as directed by the MRO as part of the verification process, or as directed by the DER under §40.193(d). In the case of a pre-employment drug test, the employee is deemed to have refused to test on this basis only if the pre-employment test is conducted following a contingent offer of employment. If there was no contingent offer of employment, the MRO will cancel the test; or

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

(9) For an observed collection, fail to follow the observer's instructions to raise your clothing above the waist, lower clothing and underpants, and to turn around to permit the observer to determine if you have any type of prosthetic or other device that could be used to interfere with the collection process.

(10) Possess or wear a prosthetic or other device that could be used to interfere with the collection process.

(11) Admit to the collector or MRO that you adulterated or substituted the specimen.

(b) As an employee, if the MRO reports that you have a verified adulterated or substituted test result, you have refused to take a drug test.

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

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

(1) As the collector, you must note the refusal in the "Remarks" line (Step 2), and sign and date the CCF.

(2) As the MRO, you must note the refusal by checking the "refused to test because" box (Step 6) on Copy 2 of the CCF, and add the reason on the "Remarks" line. You must then sign and date the CCF.

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

[65 FR 79526, Dec. 19, 2000, as amended at 66 FR 41953, Aug. 9, 2001; 68 FR 31626, May 28, 2003; 71 FR 49384, Aug. 23, 2006; 73 FR 35974, June 25, 2008]

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

(a) This section prescribes procedures for situations in which an employee does not provide a sufficient amount of urine to permit a drug test (i.e., 45 mL of urine).

(b) As the collector, you must do the following:

(1) Discard the insufficient specimen, except where the insufficient specimen was out of temperature range or showed evidence of adulteration or tampering (see §40.65(b) and (c)).

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

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

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

(5) Send Copy 2 of the CCF to the MRO and Copy 4 to the DER. You must send or fax these copies to the MRO and DER within 24 hours or the next business day.

(c) As the DER, when the collector informs you that the employee has not provided a sufficient amount of urine (see paragraph (b)(4) of this section), you must, after consulting with the MRO, direct the employee to obtain, within five days, an evaluation from a licensed physician, acceptable to the MRO, who has expertise in the medical issues raised by the employee's failure to provide a sufficient specimen. (The MRO may perform this evaluation if the MRO has appropriate expertise.)

(1) As the MRO, if another physician will perform the evaluation, you must provide the other physician with the following information and instructions:

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

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

(iii) That the referral physician must agree to follow the requirements of paragraphs (d) through (g) of this section.

(2) [Reserved]

(d) As the referral physician conducting this evaluation, you must recommend that the MRO make one of the following determinations:

(1) A medical condition has, or with a high degree of probability could have, precluded the employee from providing a sufficient amount of urine. As the MRO, if you accept this recommendation, you must:

(i) Check "Test Cancelled" (Step 6) on the CCF; and

(ii) Sign and date the CCF.

(2) There is not an adequate basis for determining that a medical condition has, or with a high degree of probability could have, precluded the employee from providing a sufficient amount of urine. As the MRO, if you accept this recommendation, you must:

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

(ii) Sign and date the CCF.

(e) For purposes of this paragraph, a medical condition includes an ascertainable physiological condition (e.g., a urinary system dysfunction) or a medically documented pre-existing psychological disorder, but does not include unsupported assertions of "situational anxiety" or dehydration.

(f) As the referral physician making the evaluation, after completing your evaluation, you must provide a written statement of your recommendations and the basis for them to the MRO. You must not include in this statement detailed information on the employee's medical condition beyond what is necessary to explain your conclusion.

(g) If, as the referral physician making this evaluation in the case of a pre-employment test, you determine that the employee's medical condition is a serious and permanent or long-term disability that is highly likely to prevent the employee from providing a sufficient amount of urine for a very long or indefinite period of time, you must set forth your determination and the reasons for it in your written statement to the MRO. As the MRO, upon receiving such a report, you must follow the requirements of §40.195, where applicable.

(h) As the MRO, you must seriously consider and assess the referral physician's recommendations in making your determination about whether the employee has a medical condition that has, or with a high degree of probability could have, precluded the employee from providing a sufficient amount of urine. You must report your determination to the DER in writing as soon as you make it.

(i) As the employer, when you receive a report from the MRO indicating that a test is cancelled as provided in paragraph (d)(1) of this section, you take no further action with respect to the employee. The employee remains in the random testing pool.

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

§ 40.195 What happens when an individual is unable to provide a sufficient amount of urine for a pre-employment follow-up or return-to-duty test because of a permanent or long-term medical condition?

(a) This section concerns a situation in which an employee has a medical condition that precludes him or her from providing a sufficient specimen for a pre-employment follow-up or return-to-duty test and the condition involves a permanent or long-term disability. As the MRO in this situation, you must do the following:

(1) You must determine if there is clinical evidence that the individual is an illicit drug user. You must make this determination by personally conducting, or causing to be conducted, a medical evaluation and through consultation with the employee's physician and/or the physician who conducted the evaluation under §40.193(d).

(2) If you do not personally conduct the medical evaluation, you must ensure that one is conducted by a licensed physician acceptable to you.

(3) For purposes of this section, the MRO or the physician conducting the evaluation may conduct an alternative test (e.g., blood) as part of the medically appropriate procedures in determining clinical evidence of drug use.

(b) If the medical evaluation reveals no clinical evidence of drug use, as the MRO, you must report the result to the employer as a negative test with written notations regarding results of both the evaluation conducted under §40.193(d) and any further medical examination. This report must state the basis for the determination that a permanent or long-term medical condition exists, making provision of a sufficient urine specimen impossible, and for the determination that no signs and symptoms of drug use exist.

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

(2) Sign and date the CCF.

(c) If the medical evaluation reveals clinical evidence of drug use, as the MRO, you must report the result to the employer as a cancelled test with written notations regarding results of both the evaluation conducted under §40.193(d) and any further medical examination. This report must state that a permanent or long-term medical condition exists, making provision of a sufficient urine specimen impossible, and state the reason for the determination that signs and symptoms of drug use exist. Because this is a cancelled test, it does not serve the purposes of a negative test (i.e., the employer is not authorized to allow the employee to begin or resume performing safety-sensitive functions, because a negative test is needed for that purpose).

(d) For purposes of this section, permanent or long-term medical conditions are those physiological, anatomic, or psychological abnormalities documented as being present prior to the attempted collection, and considered not amenable to correction or cure for an extended period of time, if ever.

(1) Examples would include destruction (any cause) of the glomerular filtration system leading to renal failure; unrepaired traumatic disruption of the urinary tract; or a severe psychiatric disorder focused on genito-urinary matters.

(2) Acute or temporary medical conditions, such as cystitis, urethritis or prostatitis, though they might interfere with collection for a limited period of time, cannot receive the same exceptional consideration as the permanent or long-term conditions discussed in paragraph (d)(1) of this section.

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

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

(a) As the employer, if the MRO informs you that a positive drug test was dilute, you simply treat the test as a verified positive test. You must not direct the employee to take another test based on the fact that the specimen was dilute.

(b) As an employer, if the MRO informs you that a negative test was dilute, take the following action:

(1) If the MRO directs you to conduct a recollection under direct observation (i.e., because the creatinine concentration of the specimen was equal to or greater than 2mg/dL, but less than or equal to 5 mg/dL (see §40.155(c)), you must do so immediately.

(2) Otherwise (i.e., if the creatinine concentration of the dilute specimen is greater than 5 mg/dL), you may, but are not required to, direct the employee to take another test immediately.

(i) Such recollections must not be collected under direct observation, unless there is another basis for use of direct observation (see §40.67 (b) and (c)).

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

(c) The following provisions apply to all tests you direct an employee to take under paragraph (b) of this section:

(1) You must ensure that the employee is given the minimum possible advance notice that he or she must go to the collection site;

(2) You must treat the result of the test you directed the employee to take under paragraph (b) of this section—and not a prior test—as the test result of record, on which you rely for purposes of this part;

(3) If the result of the test you directed the employee to take under paragraph (b)(1) of this section is also negative and dilute, you are not permitted to make the employee take an additional test because the result was dilute.

(4) If the result of the test you directed the employee to take under paragraph (b)(2) of this section is also negative and dilute, you are not permitted to make the employee take an additional test because the result was dilute. Provided, however, that if the MRO directs you to conduct a recollection under direct observation under paragraph (b)(1) of this section, you must immediately do so.

(5) If the employee declines to take a test you directed him or her to take under paragraph (b) of this section, the employee has refused the test for purposes of this part and DOT agency regulations.
[68 FR 31626, May 28, 2003; 69 FR 64867, Nov.9, 2004; 73 FR 35974, June 25, 2008]

§ 40.199 What problems always cause a drug test to be cancelled?

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

(b) The following are "fatal flaws":

(1) There is no printed collector's name and no collector's signature;

(2) The specimen ID numbers on the specimen bottle and the CCF do not match;

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

(4) Because of leakage or other causes, there is an insufficient amount of urine in the primary specimen bottle for analysis and the specimens cannot be redesignated (see §40.83(g)).

(c) You must report the result as provided in §40.161 .

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

As the MRO, you must cancel a drug test when a laboratory reports that any of the following problems have occurred. You must inform the DER that the test was cancelled. You must also direct the DER to ensure that an additional collection occurs immediately, if required by the applicable procedures specified in paragraphs (a) through (e) of this section.

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

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

(c) The laboratory reports that the split specimen failed to reconfirm all of the primary specimen results because the drug(s)/drug metabolite(s) were not detected; adulteration criteria were not met; and/ or substitution criteria were not met. You must follow the applicable procedures in § 40.187(b) – no recollection is required in this case, unless the split specimen creatinine concentration for a substituted primary specimen was greater than or equal to 2mg/dL but less than or equal to 5mg/ dL, or the primary specimen had an invalid result which was not reported to the DER. Both these cases require recollection under direct observation.

(d) The laboratory reports that the split specimen failed to reconfirm all of the primary specimen results, and that the split specimen was invalid. You must follow the procedures in § 40.187(c)(1) – recollection under direct observation is required in this case.

(e) The laboratory reports that the split specimen failed to reconfirm all of the primary specimen results because the split specimen was not available for testing or there was no split laboratory available to test the specimen. You must follow the applicable procedures in § 40.187(e) – recollection under direct observation is required in this case.

(f) The examining physician has determined that there is an acceptable medical explanation of the employee's failure to provide a sufficient amount of urine. You must follow applicable procedures in §40.193(d)(1) (no recollection is required in this case).
[65 FR 79526, Dec. 19, 2000, as amended at 73 FR 35974, June 25, 2008]

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

(a) As the MRO, when a laboratory discovers a "correctable flaw" during its processing of incoming specimens (see §40.83), the laboratory will attempt to correct it. If the laboratory is unsuccessful in this attempt, it will report to you that the specimen has been "Rejected for Testing" (with the reason stated).

(b) The following is a "correctable flaw" that laboratories must attempt to correct: The collector's signature is omitted on the certification statement on the CCF.

(c) As the MRO, when you discover a "correctable flaw" during your review of the CCF, you must cancel the test unless the flaw is corrected.

(d) The following are correctable flaws that you must attempt to correct:

(1) The employee's signature is omitted from the certification statement, unless the employee's failure or refusal to sign is noted on the "Remarks" line of the CCF.

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

(3) The collector uses a non-Federal form or an expired Federal form for the test. This flaw may be corrected through the procedure set forth in §40.205(b)(2), provided that the collection testing process has been conducted in accordance with the procedures of this part in an HHS-certified laboratory. During the period August 1–October 31, 2001, you are not required to cancel a test because of the use of an expired Federal form. Beginning November 1, 2001, if the problem is not corrected, you must cancel the test.
[65 FR 79526, Dec. 19, 2000, as amended at 66 FR 41954, Aug. 9, 2001]

§ 40.205 How are drug test problems corrected?

(a) As a collector, you have the responsibility of trying to successfully complete a collection procedure for each employee.

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

(2) If another collection is necessary, you must begin the new collection procedure as soon as possible, using a new CCF and a new collection kit.

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

(1) If the problem resulted from the omission of required information, you must, as the person responsible for providing that information, supply in writing the missing information and a statement that it is true and accurate. For example, suppose you are a collector, and you forgot to make a notation on the "Remarks" line of the CCF that the employee did not sign the certification. You would, when the problem is called to your attention, supply a signed statement that the employee failed or refused to sign the certification and that your statement is true and accurate. You must supply this information on the same business day on which you are notified of the problem, transmitting it by fax or courier.

(2) If the problem is the use of a non-Federal form or an expired Federal form, you must provide a signed statement (i.e., a memorandum for the record). It must state that the incorrect form contains all the information needed for a valid DOT drug test, and that the incorrect form was used inadvertently or as the only means of conducting a test, in circumstances beyond your control. The statement must also list the steps you have taken to prevent future use of non-Federal forms or expired Federal forms for DOT tests. For this flaw to

be corrected, the test of the specimen must have occurred at a HHS-certified laboratory where it was tested consistent with the requirements of this part. You must supply this information on the same business day on which you are notified of the problem, transmitting it by fax or courier.

(3) You must maintain the written documentation of a correction with the CCF.

(4) You must mark the CCF in such a way (e.g., stamp noting correction) as to make it obvious on the face of the CCF that you corrected the flaw.

(c) If the correction does not take place, as the MRO you must cancel the test.

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

§ 40.207 What is the effect of a cancelled drug test?

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

(1) As an employer, you must not attach to a cancelled test the consequences of a positive test or other violation of a DOT drug testing regulation (e.g., removal from a safety-sensitive position).

(2) As an employer, you must not use a cancelled test for the purposes of a negative test to authorize the employee to perform safety-sensitive functions (i.e., in the case of a pre-employment, return-to-duty, or follow-up test).

(3) However, as an employer, you must not direct a recollection for an employee because a test has been cancelled, except in the situations cited in paragraph (a)(2) of this section or other provisions of this part that require another test to be conducted (e.g., §§40.159(a)(5) and 40.187(b)(2), (c)(1), and (e)).

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

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

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

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

(a) If, as a laboratory, collector, employer, or other person implementing the DOT drug testing program, you become aware that the specimen temperature on the CCF was not checked and the "Remarks" line did not contain an entry regarding the temperature being out of range, you must take corrective action, including securing a memorandum for the record explaining the problem and taking appropriate action to ensure that the problem does not recur.

(b) This error does not result in the cancellation of the test.

(c) As an employer or service agent, this error, even though not sufficient to cancel a drug test result, may subject you to enforcement action under DOT agency regulations or Subpart R of this part.

[66 FR 41954, Aug. 9, 2001]

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

(a) As a collector, laboratory, MRO, employer or other person administering the drug testing process, you must document any errors in the testing process of which you become aware, even if they are not considered problems that will cause a test to be cancelled as listed in this subpart. Decisions about the ultimate impact of these errors will be determined by other administrative or legal proceedings, subject to the limitations of paragraph (b) of this section.

(b) No person concerned with the testing process may declare a test cancelled based on an error that does not have a significant adverse effect on the right of the employee to have a fair and accurate test. Matters that do not result in the cancellation of a test include, but are not limited to, the following:

(1) A minor administrative mistake (e.g., the omission of the employee's middle initial, a transposition of numbers in the employee's social security number);

(2) An error that does not affect employee protections under this part (e.g., the collector's failure to add bluing agent to the toilet bowl, which adversely affects only the ability of the collector to detect tampering with the specimen by the employee);

(3) The collection of a specimen by a collector who is required to have been trained (see §40.33), but who has not met this requirement;

(4) A delay in the collection process (see §40.61(a));

(5) Verification of a test result by an MRO who has the basic credentials to be qualified as an MRO (see §40.121(a) through (b)) but who has not met training and/or documentation requirements (see §40.121(c) through (e));

(6) The failure to directly observe or monitor a collection that the rule requires or permits to be directly observed or monitored, or the unauthorized use of direct observation or monitoring for a collection;

(7) The fact that a test was conducted in a facility that does not meet the requirements of §40.41;

(8) If the specific name of the courier on the CCF is omitted or erroneous;

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

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

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

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

Subpart J - Alcohol Testing Personnel

§ 40.211 Who conducts DOT alcohol tests?

(a) Screening test technicians (STTs) and breath alcohol technicians (BATs) meeting their respective requirements of this subpart are the only people authorized to conduct DOT alcohol tests.

(b) An STT can conduct only alcohol screening tests, but a BAT can conduct alcohol screening and confirmation tests.

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

§ 40.213 What training requirements must STTs and BATs meet?

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

(a) Basic information. You must be knowledgeable about the alcohol testing procedures in this part and the current DOT guidance. These documents and information are available from ODAPC (Department of Transportation, 1200 New Jersey Avenue, SE, Washington DC, 20590, 202–366–3784, or on the ODAPC web site (*http://www.dot.gov/ost/dapc*).

(b) Qualification training. You must receive qualification training meeting the requirements of this paragraph (b).

(1) Qualification training must be in accordance with the DOT Model BAT or STT Course, as applicable. The DOT Model Courses are available from ODAPC (Department of Transportation, 1200 New Jersey Avenue, SE, Washington DC, 20590, 202–366–3784, or on the ODAPC web site (*http://www.dot.gov/ost/dapc)*. The training can also be provided using a course of instruction equivalent to the DOT Model Courses. On request, ODAPC will review BAT and STT instruction courses for equivalency.

(2) Qualification training must include training to proficiency in using the alcohol testing procedures of this part and in the operation of the particular alcohol testing device(s) (i.e., the ASD(s) or EBT(s)) you will be using.

(3) The training must emphasize that you are responsible for maintaining the integrity of the testing process, ensuring the privacy of employees being tested, and avoiding conduct or statements that could be viewed as offensive or inappropriate.

(4) The instructor must be an individual who has demonstrated necessary knowledge, skills, and abilities by regularly conducting DOT alcohol tests as an STT or BAT, as applicable, for a period of at least a year, who has conducted STT or BAT training, as applicable, under this part for a year, or who has successfully completed a "train the trainer" course.

(c) Initial Proficiency Demonstration. Following your completion of qualification training under paragraph (b) of this section, you must demonstrate proficiency in alcohol testing under this part by completing seven consecutive error-free mock tests (BATs) or five consecutive error-free tests (STTs).

(1) Another person must monitor and evaluate your performance, in person or by a means that provides real-time observation and interaction between the instructor and trainee, and attest in writing that the mock collections are "error-free." This person must be an individual who meets the requirements of paragraph (b)(4) of this section.

(2) These tests must use the alcohol testing devices (e.g., EBT(s) or ASD(s)) that you will use as a BAT or STT.

(3) If you are an STT who will be using an ASD that indicates readings by changes, contrasts, or other readings in color, you must demonstrate as part of the mock test that you are able to discern changes, contrasts, or readings correctly.

(d) Schedule for qualification training and initial proficiency demonstration. The following is the schedule for qualification training and the initial proficiency demonstration you must meet:

(1) If you became a BAT or STT before August 1, 2001, you were required to have met the requirements set forth in paragraphs (b) and (c) of this section, and you do not have to meet them again.

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

(e) Refresher training. No less frequently than every five years from the date on which you satisfactorily complete the requirements of paragraphs (b) and (c) of this section, you must complete refresher training that meets all the requirements of paragraphs (b) and (c) of this section. If you are a BAT or STT who completed qualification training before January 1, 1998, you are not required to complete refresher training until January 1, 2003.

(f) Error Correction Training. If you make a mistake in the alcohol testing process that causes a test to be cancelled (i.e., a fatal or uncorrected flaw), you must undergo error correction training. This training must occur within 30 days of the date you are notified of the error that led to the need for retraining.

(1) Error correction training must be provided and your proficiency documented in writing by a person who meets the requirements of paragraph (b)(4) of this section.

(2) Error correction training is required to cover only the subject matter area(s) in which the error that caused the test to be cancelled occurred.

(3) As part of the error correction training, you must demonstrate your proficiency in the alcohol testing procedures of this part by completing three consecutive error-free mock tests. The mock tests must include one uneventful scenario and two scenarios related to the area(s) in which your error(s) occurred. The person providing the training must monitor and evaluate your performance and attest in writing that the mock tests were error-free.

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

(h) Other persons who may serve as BATs or STTs. (1) Anyone meeting the requirements of this section to be a BAT may act as an STT, provided that the individual has demonstrated initial proficiency in the operation of the ASD that he or she is using, as provided in paragraph (c) of this section.

(2) Law enforcement officers who have been certified by state or local governments to conduct breath alcohol testing are deemed to be qualified as BATs. They are not required to also complete the training requirements of this section in order to act as BATs. In order for a test conducted by such an officer to be accepted under DOT alcohol testing requirements, the officer must have been certified by a state or local government to use the EBT or ASD that was used for the test.
[65 FR 79526, Dec. 19, 2000, as amended at 66 FR 41954, Aug. 9, 2001; 73 FR 33329, June 12, 2008]

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

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

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

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

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

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

§ 40.221 Where does an alcohol test take place?

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

§ 40.225 What form is used for an alcohol test?

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

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

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

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

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

(4) You may use an ATF in which all pages are printed on white paper. You may modify the ATF by using colored paper, or have clearly discernable borders or designation statements on Copy 2 and Copy 3. When colors are used, they must be green for Copy 2 and blue for Copy 3.

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

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

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

[65 FR 79526, Dec. 19, 2000, as amended at 66 FR 41954, Aug. 9, 2001; 75 FR 8528, February 25, 2010]

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

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

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

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

EBTs and ASDs on the NHTSA conforming products lists (CPL) for evidential and non-evidential devices are the only devices you are allowed to use to conduct alcohol screening tests under this part. You may use an ASD that is on the NHTSA CPL for DOT alcohol tests only if there are instructions for its use in this part. An ASD can be used only for screening tests for alcohol, and may not be used for confirmation tests. [65 FR 79526, Dec. 19, 2000, as amended at 66 FR 41954, Aug. 9, 2001]

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

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

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

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

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

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

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

(5) Tests an air blank; and

(6) Performs an external calibration check.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Subpart L—Alcohol Screening Tests

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

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

(a) When a specific time for an employee's test has been scheduled, or the collection site is at the employee's 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, you must notify the DER that the employee has not reported for testing. In a situation where a C/TPA has notified an owner/operator or other individual employee to report for testing and the employee does not appear, the C/TPA must notify the employee that he or she has refused to test.

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

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

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

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

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

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

(f) Complete Step 1 of the ATF.

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

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

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

(a) Select, or allow the employee to select, an individually wrapped or sealed mouthpiece from the testing materials.

(b) Open the individually wrapped or sealed mouthpiece in view of the employee and insert it into the device in accordance with the manufacturer's instructions.

(c) Instruct the employee to blow steadily and forcefully into the mouthpiece for at least six seconds or until the device indicates that an adequate amount of breath has been obtained.

(d) Show the employee the displayed test result.

(e) If the device is one that prints the test number, testing device name and serial number, time, and result directly onto the ATF, you must check to ensure that the information has been printed correctly onto the ATF.

(f) If the device is one that prints the test number, testing device name and serial number, time and result, but on a separate printout rather than directly onto the ATF, you must affix the printout of the information to the designated space on the ATF with tamper-evident tape or use a self-adhesive label that is tamper-evident.

(g) If the device is one that does not print the test number, testing device name and serial number, time, and result, or it is a device not being used with a printer, you must record this information in Step 3 of the ATF.

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

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

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

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

(3) Offer the employee the opportunity to use the device. If the employee uses it, you must instruct the employee to insert it into his or her mouth and use it in a manner described by the device's manufacturer.

(4) If the employee chooses not to use the device, or in all cases in which a new test is necessary because the device did not activate (see paragraph (a)(7) of this section), you must insert the device into the employee's mouth and gather saliva in the manner described by the device's manufacturer. You must wear single-use examination or similar gloves while doing so and change them following each test.

(5) When the device is removed from the employee's mouth, you must follow the manufacturer's instructions regarding necessary next steps in ensuring that the device has activated.

(6)(i) If you were unable to successfully follow the procedures of paragraphs (a)(3) through (a)(5) of this section (e.g., the device breaks, you drop the device on the floor), you must discard the device and conduct a new test using a new device.

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

(iii) You must note on the "Remarks" line of the ATF the reason for the new test. (Note: You may continue using the same ATF with which you began the test.)

(iv) You must offer the employee the choice of using the device or having you use it unless the employee, in the opinion of the STT or BAT, was responsible (e.g., the employee dropped the device) for the new test needing to be conducted.

(v) If you are unable to successfully follow the procedures of paragraphs (a)(3) through (a)(5) of this section on the new test, you must end the collection and put an explanation on the "Remarks" line of the ATF.

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

(7) If you are able to successfully follow the procedures of paragraphs (a)(3)—(a)(5) of this section, but the device does not activate, you must discard the device and conduct a new test, in the same manner as provided in paragraph (a)(6) of this section. In this case, you must place the device into the employee's mouth to collect saliva for the new test.

(8) You must read the result displayed on the device no sooner than the device's manufacturer instructs. In all cases the result displayed must be read within 15 minutes of the test. You must then show the device and it's reading to the employee and enter the result on the ATF.

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

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

(b) As the STT or BAT, you must take the following steps when using the breath tube ASD:

(1) Check the expiration date on the detector device and the electronic analyzer or on the package containing the device and the analyzer and show it to the employee. You must not use the device or the analyzer after their expiration date. You must not use an analyzer which is not specifically pre-calibrated for the device being used in the collection.

(2) Remove the device from the package and secure an inflation bag onto the appropriate end of the device, as directed by the manufacturer on the device's instructions.

(3) Break the tube's ampoule in the presence of the employee.

(4) Offer the employee the opportunity to use the device. If the employee chooses to use (e.g. hold) the device, instruct the employee to blow forcefully and steadily into the blowing end of device until the inflation bag fills with air (approximately 12 seconds).

(5) If the employee chooses not to hold the device, you must hold it and provide the use instructions in paragraph (b)(4) of this section.

(6) When the employee completes the breath process, take the device from the employee (or if you were holding it, remove it from the employee's mouth), remove the inflation bag, and prepare the device to be read by the analyzer in accordance with the manufacturer's directions.

(7)(i) If you were unable to successfully follow the procedures of paragraphs (b)(4) through (b)(6) of this section (e.g., the device breaks apart, the employee did not fill the inflation bag), you must discard the device and conduct a new test using a new one.

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

(iii) You must note on the "Remarks" line of the ATF the reason for the new test. (Note: You may continue using the same ATF with which you began the test.)

(iv) You must offer the employee the choice of holding the device or having you hold it unless the employee, in the your opinion, was responsible (e.g., the employee failed to fill the inflation bag) for the new test needing to be conducted.

(v) If you are unable to successfully follow the procedures of paragraphs (b)(4) through (b)(6) of this section on the new test, you must end the collection and put an explanation on the "Remarks" line of the ATF.

(vi) You must then direct the employee to take a new test immediately, using another type of ASD (e.g., saliva device) or an EBT.

(8) If you were able to successfully follow the procedures of paragraphs (b)(4) through (b)(6) of this section and after having waited the required amount of time directed by the manufacturer for the detector device to incubate, you must place the device in the analyzer in accordance with the manufacturer's directions. The

result must be read from the analyzer no earlier then the required incubation time of the device. In all cases, the result must be read within 15 minutes of the test.

(9) You must follow the manufacturer's instructions for determining the result of the test. You must show the analyzer result to the employee and record the result on Step 3 of the ATF.

(10) You must never re-use detector devices or any gloves used in breath tube testing. The inflation bag must be voided of air following removal from a device. Inflation bags and electronic analyzers may be re-used but only in accordance with the manufacturer's directions.

(11) You must note the fact that you used a breath tube device in Step 3 of the ATF.

[67 FR 61522, Oct. 1, 2002, as amended at 72 FR 1299, Jan. 11, 2007; 75 FR 8526, February25, 2010]

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Subpart M - Alcohol Confirmation Tests

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(c) Complete Step 1 of the ATF.

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

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

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

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

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

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

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

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

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

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

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

(b) You must open a new individually wrapped or sealed mouthpiece in view of the employee and insert it into the device in accordance with the manufacturer's instructions.

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

(d) You must instruct the employee to blow steadily and forcefully into the mouthpiece for at least six seconds or until the device indicates that an adequate amount of breath has been obtained.

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

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

(g) If the EBT provides a separate printout of the result, you must attach the printout to the designated space on the ATF with tamper-evident tape, or use a self-adhesive label that is tamper-evident.
[65 FR 79526, Dec. 19, 2000, as amended at 66 FR 41954, Aug. 9, 2001]

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

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

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

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

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

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

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

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

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

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

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

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

Subpart N - Problems in Alcohol Testing

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

(a) As an employee, you are considered to have refused to take an alcohol test if you:

(1) Fail to appear for any test (except a pre-employment test) within a reasonable time, as determined by the employer, consistent with applicable DOT agency regulations, after being directed to do so by the employer. This includes the failure of an employee (including an owner-operator) to appear for a test when called by a C/TPA (see §40.241(a));

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

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

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

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

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

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

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

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

(d) As an employee, when you refuse to take a non-DOT test or to sign a non-DOT form, you have not refused to take a DOT test. There are no consequences under DOT agency regulations for such a refusal.
[65 FR 79526, Dec. 19, 2000, as amended at 66 FR 41954, Aug. 9, 2001]

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

(a) As the STT, you must take the following steps if an employee is unable to provide sufficient saliva to complete a test on a saliva screening device (e.g., the employee does not provide sufficient saliva to activate the device).

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

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

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

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

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

(a) If an employee does not provide a sufficient amount of breath to permit a valid breath test, you must take the steps listed in this section.

(b) As the BAT or STT, you must instruct the employee to attempt again to provide a sufficient amount of breath and about the proper way to do so.

(1) If the employee refuses to make the attempt, you must discontinue the test, note the fact on the "Remarks" line of the ATF, and immediately notify the DER. This is a refusal to test.

(2) If the employee again attempts and fails to provide a sufficient amount of breath, you may provide another opportunity to the employee to do so if you believe that there is a strong likelihood that it could result in providing a sufficient amount of breath.

(3) When the employee's attempts under paragraph (b)(2) of this section have failed to produce a sufficient amount of breath, you must note the fact on the "Remarks" line of the ATF and immediately notify the DER.

(4) If you are using an EBT that has the capability of operating manually, you may attempt to conduct the test in manual mode.

(5) If you are qualified to use a saliva ASD and you are in the screening test stage, you may change to a saliva ASD only to complete the screening test.

(c) As the employer, when the BAT or STT informs you that the employee has not provided a sufficient amount of breath, you must direct the employee to obtain, within five days, an evaluation from a licensed physician who is acceptable to you and who has expertise in the medical issues raised by the employee's failure to provide a sufficient specimen.

(1) You are required to provide the physician who will conduct the evaluation with the following information and instructions:

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

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

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

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

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

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

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

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

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

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

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

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

(1) The STT or BAT reads the result either sooner than or later than the time allotted by the manufacturer and this Part (see §40.245(a)(8) for the saliva ASD and §40.245(b)(8) for the breath tube ASD).

(2) The saliva ASD does not activate (see §40.245(a)(7); or

(3) The device is used for a test after the expiration date printed on the device or on its package (see §40.245(a)(1) for the saliva ASD and §40.245(b)(1) for the breath tube ASD).

(4) The breath tube ASD is tested with an analyzer which has not been pre-calibrated for that device's specific lot (see §40.245(b)(1)).

(b) In the case of a screening or confirmation test conducted on an EBT, the sequential test number or alcohol concentration displayed on the EBT is not the same as the sequential test number or alcohol concentration on the printed result (see §40.253(c), (e) and (f)).

(c) In the case of a confirmation test:

(1) The BAT conducts the confirmation test before the end of the minimum 15-minute waiting period (see §40.251(a)(1));

(2) The BAT does not conduct an air blank before the confirmation test (see §40.253(a));

(3) There is not a 0.00 result on the air blank conducted before the confirmation test (see §40.253(a)(1) and (2));

(4) The EBT does not print the result (see §40.253(f)); or

(5) The next external calibration check of the EBT produces a result that differs by more than the tolerance stated in the QAP from the known value of the test standard. In this case, every result of 0.02 or above obtained on the EBT since the last valid external calibration check is cancelled (see §40.233(a)(1) and (c)(3)). [65 FR 79526, Dec. 19, 2000, as amended at 67 FR 61522, Oct. 1, 2002; 71 FR 49384. Aug. 23, 2006; 72 FR 1299, Jan. 11, 2007; 75 FR 8526, February 25, 2010]

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

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

(a) The BAT or STT does not sign the ATF (see §§40.247(a)(1) and 40.255(a)(1)).

(b) The BAT or STT fails to note on the "Remarks" line of the ATF that the employee has not signed the ATF after the result is obtained (see §40.255(a)(3)).

(c) The BAT or STT uses a non-DOT form for the test (see §40.225(a)).

[65 FR 79526, Dec. 19, 2000, amended at 71 FR 49384, Aug. 23, 2006]

§ 40.271 How are alcohol testing problems corrected?

(a) As a BAT or STT, you have the responsibility of trying to complete successfully an alcohol test for each employee.

(1) If, during or shortly after the testing process, you become aware of any event that will cause the test to be cancelled (see §40.267), you must try to correct the problem promptly, if practicable. You may repeat the testing process as part of this effort.

(2) If repeating the testing process is necessary, you must begin a new test as soon as possible. You must use a new ATF, a new sequential test number, and, if needed, a new ASD and/or a new EBT. It is permissible to use additional technical capabilities of the EBT (e.g., manual operation) if you have been trained to do so in accordance with §40.213(c) .

(3) If repeating the testing process is necessary, you are not limited in the number of attempts to complete the test, provided that the employee is making a good faith effort to comply with the testing process.

(4) If another testing device is not available for the new test at the testing site, you must immediately notify the DER and advise the DER that the test could not be completed. As the DER who receives this information, you must make all reasonable efforts to ensure that the test is conducted at another testing site as soon as possible.

(b) If, as an STT, BAT, employer or other service agent administering the testing process, you become aware of a "correctable flaw" (see §40.269) that has not already been corrected, you must take all practicable action to correct the problem so that the test is not cancelled.

(1) If the problem resulted from the omission of required information, you must, as the person responsible for providing that information, supply in writing the missing information and a signed statement that it is true and accurate. For example, suppose you are a BAT and you forgot to make a notation on the "Remarks" line of the ATF that the employee did not sign the certification. You would, when the problem is called to your attention, supply a signed statement that the employee failed or refused to sign the certification after the result was obtained, and that your signed statement is true and accurate.

(2) If the problem is the use of a non-DOT form, you must, as the person responsible for the use of the incorrect form, certify in writing that the incorrect form contains all the information needed for a valid DOT alcohol test. You must also provide a signed statement that the incorrect form was used inadvertently or as the only means of conducting a test, in circumstances beyond your control, and the steps you have taken to prevent future use of non-DOT forms for DOT tests. You must supply this information on the same business day on which you are notified of the problem, transmitting it by fax or courier.

(c) If you cannot correct the problem, you must cancel the test.

§ 40.273 What is the effect of a cancelled alcohol test?

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

(1) As an employer, you must not attach to a cancelled test the consequences of a test result that is 0.02 or greater (e.g., removal from a safety-sensitive position).

(2) As an employer, you must not use a cancelled test in a situation where an employee needs a test result that is below 0.02 (e.g., in the case of a return-to-duty or follow-up test to authorize the employee to perform safety-sensitive functions).

(3) As an employer, you must not direct a recollection for an employee because a test has been cancelled, except in the situations cited in paragraph (a)(2) of this section or other provisions of this part.

(b) A cancelled test does not count toward compliance with DOT requirements, such as a minimum random testing rate.

(c) When a test must be cancelled, if you are the BAT, STT, or other person who determines that the cancellation is necessary, you must inform the affected DER within 48 hours of the cancellation.

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

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

(a) As an STT, BAT, employer, or a service agent administering the testing process, you must document any errors in the testing process of which you become aware, even if they are not "fatal flaws" or "correctable flaws" listed in this subpart. Decisions about the ultimate impact of these errors will be determined by administrative or legal proceedings, subject to the limitation of paragraph (b) of this section.

(b) No person concerned with the testing process may declare a test cancelled based on a mistake in the process that does not have a significant adverse effect on the right of the employee to a fair and accurate test. For example, it is inconsistent with this part to cancel a test based on a minor administrative mistake (e.g., the omission of the employee's middle initial) or an error that does not affect employee protections under this part. Nor does the failure of an employee to sign in Step 4 of the ATF result in the cancellation of the test. Nor is a test to be cancelled on the basis of a claim by an employee that he or she was improperly selected for testing.

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

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

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

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

§ 40.281 Who is qualified to act as a SAP?

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

(a) Credentials. You must have one of the following credentials:

(1) You are a licensed physician (Doctor of Medicine or Osteopathy);

(2) You are a licensed or certified social worker;

(3) You are a licensed or certified psychologist;

(4) You are a licensed or certified employee assistance professional;

(5) You are a state-licensed or certified marriage and family therapist; or

(6) You are a drug and alcohol counselor certified by the National Association of Alcoholism and Drug Abuse Counselors Certification Commission (NAADAC); or by the International Certification Reciprocity Consortium/Alcohol and Other Drug Abuse (ICRC); or by the National Board for Certified Counselors, Inc. and Affiliates/Master Addictions Counselor (NBCC).

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

(1) You must be knowledgeable about and have clinical experience in the diagnosis and treatment of alcohol and controlled substances-related disorders.

(2) You must be knowledgeable about the SAP function as it relates to employer interests in safety-sensitive duties.

(3) You must be knowledgeable about this part, the DOT agency regulations applicable to the employers for whom you evaluate employees, and the DOT SAP Guidelines, and you keep current on any changes to these materials. These documents are available from ODAPC (Department of Transportation, 1200 New Jersey Avenue, SE, Washington DC, 20590, 202–366–3784, or on the ODAPC web site (*http://www.dot.gov/ost/dapc*).

(c) Qualification training. You must receive qualification training meeting the requirements of this paragraph (c).

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

(i) Background, rationale, and coverage of the Department's drug and alcohol testing program;

(ii) 49 CFR Part 40 and DOT agency drug and alcohol testing rules;

(iii) Key DOT drug testing requirements, including collections, laboratory testing, MRO review, and problems in drug testing;

(iv) Key DOT alcohol testing requirements, including the testing process, the role of BATs and STTs, and problems in alcohol tests;

(v) SAP qualifications and prohibitions;

(vi) The role of the SAP in the return-to-duty process, including the initial employee evaluation, referrals for education and/or treatment, the follow-up evaluation, continuing treatment recommendations, and the follow-up testing plan;

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

(viii) Reporting and recordkeeping requirements;

(ix) Issues that SAPs confront in carrying out their duties under the program.

(2) Following your completion of qualification training under paragraph (c)(1) of this section, you must satisfactorily complete an examination administered by a nationally-recognized professional or training organization. The examination must comprehensively cover all the elements of qualification training listed in paragraph (c)(1) of this section.

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

(i) If you became a SAP before August 1, 2001, you must meet the qualification training requirement no later than December 31, 2003.

(ii) If you become a SAP between August 1, 2001, and December 31, 2003, you must meet the qualification training requirement no later than December 31, 2003.

(iii) If you become a SAP on or after January 1, 2004, you must meet the qualification training requirement before you begin to perform SAP functions.

(d) Continuing education. During each three-year period from the date on which you satisfactorily complete the examination under paragraph (c)(2) of this section, you must complete continuing education consisting of at least 12 professional development hours (e.g., CEUs) relevant to performing SAP functions.

(1) This continuing education must include material concerning new technologies, interpretations, recent guidance, rule changes, and other information about developments in SAP practice, pertaining to the DOT program, since the time you met the qualification training requirements of this section.

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

(e) Documentation. You must maintain documentation showing that you currently meet all requirements of this section. You must provide this documentation on request to DOT agency representatives and to employers and C/TPAs who are using or contemplating using your services.

[65 FR 79526, Dec. 19, 2000, as amended at 69 FR 3022, Jan. 22, 2004; 71 FR 49384, Aug. 23, 2006; 71 FR 55347, Sept. 22, 2006; 73 FR 33329, June 12, 2008]

§ 40.283 How does a certification organization obtain recognition for its members as SAPs?

(a) If you represent a certification organization that wants DOT to authorize its certified drug and alcohol counselors to be added to §40.281(a)(6), you may submit a written petition to DOT requesting a review of your petition for inclusion.

(b) You must obtain the National Commission for Certifying Agencies (NCCA) accreditation before DOT will act on your petition.

(c) You must also meet the minimum requirements of Appendix E to this part before DOT will act on your petition.

[65 FR 79526, Dec. 19, 2000, as amended at 71 FR 49384, Aug. 23, 2006]

§ 40.285 When is a SAP evaluation required?

(a) As an employee, when you have violated DOT drug and alcohol regulations, you cannot again perform any DOT safety-sensitive duties for any employer until and unless you complete the SAP evaluation, referral, and education/treatment process set forth in this subpart and in applicable DOT agency regulations. The first step in this process is a SAP evaluation.

(b) For purposes of this subpart, a verified positive DOT drug test result, a DOT alcohol test with a result indicating an alcohol concentration of 0.04 or greater, a refusal to test (including by adulterating or substituting a urine specimen) or any other violation of the prohibition on the use of alcohol or drugs under a DOT agency regulation constitutes a DOT drug and alcohol regulation violation.

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

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

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

(a) As an employer, you are not required to provide a SAP evaluation or any subsequent recommended education or treatment for an employee who has violated a DOT drug and alcohol regulation.

(b) However, if you offer that employee an opportunity to return to a DOT safety-sensitive duty following a violation, you must, before the employee again performs that duty, ensure that the employee receives an evaluation by a SAP meeting the requirements of §40.281 and that the employee successfully complies with the SAP's evaluation recommendations.

(c) Payment for SAP evaluations and services is left for employers and employees to decide and may be governed by existing management-labor agreements and health care benefits.

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

(a) As a SAP, you are charged with:

(1) Making a face-to-face clinical assessment and evaluation to determine what assistance is needed by the employee to resolve problems associated with alcohol and/or drug use;

(2) Referring the employee to an appropriate education and/or treatment program;

(3) Conducting a face-to-face follow-up evaluation to determine if the employee has actively participated in the education and/or treatment program and has demonstrated successful compliance with the initial assessment and evaluation recommendations;

(4) Providing the DER with a follow-up drug and/or alcohol testing plan for the employee; and

(5) Providing the employee and employer with recommendations for continuing education and/or treatment.

(b) As a SAP, you are not an advocate for the employer or employee. Your function is to protect the public interest in safety by professionally evaluating the employee and recommending appropriate education/treatment, follow-up tests, and aftercare.

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

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

(a) Provide a comprehensive face-to-face assessment and clinical evaluation.

(b) Recommend a course of education and/or treatment with which the employee must demonstrate successful compliance prior to returning to DOT safety-sensitive duty.

(1) You must make such a recommendation for every individual who has violated a DOT drug and alcohol regulation.

(2) You must make a recommendation for education and/or treatment that will, to the greatest extent possible, protect public safety in the event that the employee returns to the performance of safety-sensitive functions.

(c) Appropriate education may include, but is not limited to, self-help groups (e.g., Alcoholics Anonymous) and community lectures, where attendance can be independently verified, and bona fide drug and alcohol education courses.

(d) Appropriate treatment may include, but is not limited to, in-patient hospitalization, partial in-patient treatment, out-patient counseling programs, and aftercare.

(e) You must provide a written report directly to the DER highlighting your specific recommendations for assistance (see §40.311(c)).

(f) For purposes of your role in the evaluation process, you must assume that a verified positive test result has conclusively established that the employee committed a DOT drug and alcohol regulation violation. You must not take into consideration in any way, as a factor in determining what your recommendation will be, any of the following:

(1) A claim by the employee that the test was unjustified or inaccurate;

(2) Statements by the employee that attempt to mitigate the seriousness of a violation of a DOT drug or alcohol regulation (e.g., related to assertions of use of hemp oil, "medical marijuana" use, "contact positives," poppy seed ingestion, job stress); or

(3) Personal opinions you may have about the justification or rationale for drug and alcohol testing.

(g) In the course of gathering information for purposes of your evaluation in the case of a drug-related violation, you may consult with the MRO. As the MRO, you are required to cooperate with the SAP and provide available information the SAP requests. It is not necessary to obtain the consent of the employee to provide this information.

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

(a) As an employee with a DOT drug and alcohol regulation violation, when you have been evaluated by a SAP, you must not seek a second SAP's evaluation in order to obtain another recommendation.

(b) As an employer, you must not seek a second SAP's evaluation if the employee has already been evaluated by a qualified SAP. If the employee, contrary to paragraph (a) of this section, has obtained a second SAP evaluation, as an employer you may not rely on it for any purpose under this part.

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

(a) Except as provided in paragraph (b) of this section, no one (e.g., an employer, employee, a managed-care provider, any service agent) may change in any way the SAP's evaluation or recommendations for assistance. For example, a third party is not permitted to make more or less stringent a SAP's recommendation by changing the SAP's evaluation or seeking another SAP's evaluation.

(b) The SAP who made the initial evaluation may modify his or her initial evaluation and recommendations based on new or additional information (e.g., from an education or treatment program).

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

(a) As a SAP, upon your determination of the best recommendation for assistance, you will serve as a referral source to assist the employee's entry into a education and/or treatment program.

(b) To prevent the appearance of a conflict of interest, you must not refer an employee requiring assistance to your private practice or to a person or organization from which you receive payment or to a person or organization in which you have a financial interest. You are precluded from making referrals to entities with which you are financially associated.

(c) There are four exceptions to the prohibitions contained in paragraph (b) of this section. You may refer an employee to any of the following providers of assistance, regardless of your relationship with them:

(1) A public agency (e.g., treatment facility) operated by a state, county, or municipality;

(2) The employer or a person or organization under contract to the employer to provide alcohol or drug treatment and/or education services (e.g., the employer's contracted treatment provider);

(3) The sole source of therapeutically appropriate treatment under the employee's health insurance program (e.g., the single substance abuse in-patient treatment program made available by the employee's insurance coverage plan); or

(4) The sole source of therapeutically appropriate treatment reasonably available to the employee (e.g., the only treatment facility or education program reasonably located within the general commuting area).

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

(a) As a SAP, after you have prescribed assistance under §40.293, you must re-evaluate the employee to determine if the employee has successfully carried out your education and/or treatment recommendations.

(1) This is your way to gauge for the employer the employee's ability to demonstrate successful compliance with the education and/or treatment plan.

(2) Your evaluation may serve as one of the reasons the employer decides to return the employee to safety-sensitive duty.

(b) As the SAP making the follow-up evaluation determination, you must:

(1) Confer with or obtain appropriate documentation from the appropriate education and/or treatment program professionals where the employee was referred; and

(2) Conduct a face-to-face clinical interview with the employee to determine if the employee demonstrates successful compliance with your initial evaluation recommendations.

(c) (1) If the employee has demonstrated successful compliance, you must provide a written report directly to the DER highlighting your clinical determination that the employee has done so with your initial evaluation recommendation (see §40.311(d)).

(2) You may determine that an employee has successfully demonstrated compliance even though the employee has not yet completed the full regimen of education and/or treatment you recommended or needs additional assistance. For example, if the employee has successfully completed the 30-day in-patient program you prescribed, you may make a "successful compliance" determination even though you conclude that the employee has not yet completed the out-patient counseling you recommended or should continue in an aftercare program.

(d)(1) As the SAP, if you believe, as a result of the follow-up evaluation, that the employee has not demonstrated successful compliance with your recommendations, you must provide written notice directly to the DER (see §40.311(e)).

(2) As an employer who receives the SAP's written notice that the employee has not successfully complied with the SAP's recommendations, you must not return the employee to the performance of safety-sensitive duties.

(3) As the SAP, you may conduct additional follow-up evaluation(s) if the employer determines that doing so is consistent with the employee's progress as you have reported it and with the employer's policy and/or labor-management agreements.

(4) As the employer, following a SAP report that the employee has not demonstrated successful compliance, you may take personnel action consistent with your policy and/or labor-management agreements.

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

(a) As a SAP, if you believe that ongoing services (in addition to follow-up tests) are needed to assist an employee to maintain sobriety or abstinence from drug use after the employee resumes the performance of safety-sensitive duties, you must provide recommendations for these services in your follow-up evaluation report (see §40.311(d)(10)).

(b) As an employer receiving a recommendation for these services from a SAP, you may, as part of a return-to-duty agreement with the employee, require the employee to participate in the recommended services. You may monitor and document the employee's participation in the recommended services. You may also make use of SAP and employee assistance program (EAP) services in assisting and monitoring employees' compliance with SAP recommendations. Nothing in this section permits an employer to fail to carry out its obligations with respect to follow-up testing (see §40.309).

(c) As an employee, you are obligated to comply with the SAP's recommendations for these services. If you fail or refuse to do so, you may be subject to disciplinary action by your employer.

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

(a) As the employer, if you decide that you want to permit the employee to return to the performance of safety-sensitive functions, you must ensure that the employee takes a return-to-duty test. This test cannot occur until after the SAP has determined that the employee has successfully complied with prescribed education and/or treatment. The employee must have a negative drug test result and/or an alcohol test with an alcohol concentration of less than 0.02 before resuming performance of safety-sensitive duties.

(b) As an employer, you must not return an employee to safety-sensitive duties until the employee meets the conditions of paragraph (a) of this section. However, you are not required to return an employee to safety-sensitive duties because the employee has met these conditions. That is a personnel decision that you have the discretion to make, subject to collective bargaining agreements or other legal requirements.

(c) As a SAP or MRO, you must not make a "fitness for duty" determination as part of this re-evaluation unless required to do so under an applicable DOT agency regulation. It is the employer, rather than you, who must decide whether to put the employee back to work in a safety-sensitive position.

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

(a) As a SAP, for each employee who has committed a DOT drug or alcohol regulation violation, and who seeks to resume the performance of safety-sensitive functions, you must establish a written follow-up testing plan. You do not establish this plan until after you determine that the employee has successfully complied with your recommendations for education and/or treatment.

(b) You must present a copy of this plan directly to the DER (see §40.311(d)(9)).

(c) You are the sole determiner of the number and frequency of follow-up tests and whether these tests will be for drugs, alcohol, or both, unless otherwise directed by the appropriate DOT agency regulation. For example, if the employee had a positive drug test, but your evaluation or the treatment program professionals determined that the employee had an alcohol problem as well, you should require that the employee have follow-up tests for both drugs and alcohol.

(d) However, you must, at a minimum, direct that the employee be subject to six unannounced follow-up tests in the first 12 months of safety-sensitive duty following the employee's return to safety-sensitive functions.

(1) You may require a greater number of follow-up tests during the first 12-month period of safety-sensitive duty (e.g., you may require one test a month during the 12-month period; you may require two tests per month during the first 6-month period and one test per month during the final 6-month period).

(2) You may also require follow-up tests during the 48 months of safety-sensitive duty following this first 12-month period.

(3) You are not to establish the actual dates for the follow-up tests you prescribe. The decision on specific dates to test is the employer's.

(4) As the employer, you must not impose additional testing requirements (e.g., under company authority) on the employee that go beyond the SAP's follow-up testing plan.

(e) The requirements of the SAP's follow-up testing plan "follow the employee" to subsequent employers or through breaks in service.

Example 1 to Paragraph (e): The employee returns to duty with Employer A. Two months afterward, after completing the first two of six follow-up tests required by the SAP's plan, the employee quits his job with Employer A and begins to work in a similar position for Employer B. The employee remains obligated to complete the four additional tests during the next 10 months of safety-sensitive duty, and Employer B is responsible for ensuring that the employee does so. Employer B learns of this obligation through the inquiry it makes under §40.25.

Example 2 to Paragraph (e): The employee returns to duty with Employer A. Three months later, after the employee completes the first two of six follow-up tests required by the SAP's plan, Employer A lays the employee off for economic or seasonal employment reasons. Four months later, Employer A recalls the employee. Employer A must ensure that the employee completes the remaining four follow-up tests during the next nine months.

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

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

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

(b) You should schedule follow-up tests on dates of your own choosing, but you must ensure that the tests are unannounced with no discernable pattern as to their timing, and that the employee is given no advance notice.

(c) You cannot substitute any other tests (e.g., those carried out under the random testing program) conducted on the employee for this follow-up testing requirement.

(d) You cannot count a follow-up test that has been cancelled as a completed test. A cancelled follow-up test must be recollected.

§ 40.311 What are the requirements concerning SAP reports?

(a) As the SAP conducting the required evaluations, you must send the written reports required by this section in writing directly to the DER and not to a third party or entity for forwarding to the DER (except as provided in §40.355(e)). You may, however, forward the document simultaneously to the DER and to a C/TPA.

(b) As an employer, you must ensure that you receive SAP written reports directly from the SAP performing the evaluation and that no third party or entity changed the SAP's report in any way.

(c) The SAP's written report, following an initial evaluation that determines what level of assistance is needed to address the employee's drug and/or alcohol problems, must be on the SAP's own letterhead (and not

the letterhead of another service agent) signed and dated by the SAP, and must contain the following delineated items:

(1) Employee's name and SSN;

(2) Employer's name and address;

(3) Reason for the assessment (specific violation of DOT regulations and violation date);

(4) Date(s) of the assessment;

(5) SAP's education and/or treatment recommendation; and

(6) SAP's telephone number.

(d) The SAP's written report concerning a follow-up evaluation that determines the employee has demonstrated successful compliance must be on the SAP's own letterhead (and not the letterhead of another service agent), signed by the SAP and dated, and must contain the following items:

(1) Employee's name and SSN;

(2) Employer's name and address;

(3) Reason for the initial assessment (specific violation of DOT regulations and violation date);

(4) Date(s) of the initial assessment and synopsis of the treatment plan;

(5) Name of practice(s) or service(s) providing the recommended education and/or treatment;

(6) Inclusive dates of employee's program participation;

(7) Clinical characterization of employee's program participation;

(8) SAP's clinical determination as to whether the employee has demonstrated successful compliance;

(9) Follow-up testing plan;

(10) Employee's continuing care needs with specific treatment, aftercare, and/or support group services recommendations; and

(11) SAP's telephone number.

(e) The SAP's written report concerning a follow-up evaluation that determines the employee has not demonstrated successful compliance must be on the SAP's own letterhead (and not the letterhead of another service agent), signed by the SAP and dated, and must contain the following items:

(1) Employee's name and SSN;

(2) Employer's name and address;

(3) Reason for the initial assessment (specific DOT violation and date);

(4) Date(s) of initial assessment and synopsis of treatment plan;

(5) Name of practice(s) or service(s) providing the recommended education and/or treatment;

(6) Inclusive dates of employee's program participation;

(7) Clinical characterization of employee's program participation;

(8) Date(s) of the first follow-up evaluation;

(9) Date(s) of any further follow-up evaluation the SAP has scheduled;

(10) SAP's clinical reasons for determining that the employee has not demonstrated successful compliance; and

(11) SAP's telephone number.

(f) As a SAP, you must also provide these written reports directly to the employee if the employee has no current employer and to the gaining DOT regulated employer in the event the employee obtains another transportation industry safety-sensitive position.

(g) As a SAP, you are to maintain copies of your reports to employers for 5 years, and your employee clinical records in accordance with Federal, state, and local laws regarding record maintenance, confidentiality, and release of information. You must make these records available, on request, to DOT agency representatives (e.g., inspectors conducting an audit or safety investigation) and representatives of the NTSB in an accident investigation.

(h) As an employer, you must maintain your reports from SAPs for 5 years from the date you received them.

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

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

§40.3—Definition.

§40.347—Service agent assistance with SAP-required follow-up testing.

§40.355—Transmission of SAP reports.

§40.329(c)—Making SAP reports available to employees on request.

Appendix E to Part 40—SAP Equivalency Requirements for Certification Organizations.

Subpart P - Confidentiality and Release of Information

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

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

(a) A "third party" is any person or organization to whom other subparts of this regulation do not explicitly authorize or require the transmission of information in the course of the drug or alcohol testing process.

(b) "Specific written consent" means a statement signed by the employee that he or she agrees to the release of a particular piece of information to a particular, explicitly identified, person or organization at a particular time. "Blanket releases," in which an employee agrees to a release of a category of information (e.g., all test results) or to release information to a category of parties (e.g., other employers who are members of a C/TPA, companies to which the employee may apply for employment), are prohibited under this part.

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

(a) As an employer, you may release information pertaining to an employee's drug or alcohol test without the employee's consent in certain legal proceedings.

(1) These proceedings include a lawsuit (e.g., a wrongful discharge action), grievance (e.g., an arbitration concerning disciplinary action taken by the employer), or administrative proceeding (e.g., an unemployment compensation hearing) brought by, or on behalf of, an employee and resulting from a positive DOT drug or alcohol test or a refusal to test (including, but not limited to, adulterated or substituted test results).

(2) These proceedings also include a criminal or civil action resulting from an employee's performance of safety-sensitive duties, in which a court of competent jurisdiction determines that the drug or alcohol test information sought is relevant to the case and issues an order directing the employer to produce the information. For example, in personal injury litigation following a truck or bus collision, the court could determine that a post-accident drug test result of an employee is relevant to determining whether the driver or the driver's employer was negligent. The employer is authorized to respond to the court's order to produce the records.

(b) In such a proceeding, you may release the information to the decisionmaker in the proceeding (e.g., the court in a lawsuit). You may release the information only with a binding stipulation that the decisionmaker to whom it is released will make it available only to parties to the proceeding.

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

(d) As an employer or service agent, you must immediately notify the employee in writing of any information you release under this section.

§ 40.325 [Reserved]

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

(a) As the MRO, you must, except as provided in paragraph (c) of this section, report drug test results and medical information you learned as part of the verification process to third parties without the employee's consent if you determine, in your reasonable medical judgment, that:

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

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

(b) The third parties to whom you are authorized to provide information by this section include the employer, a physician or other health care provider responsible for determining the medical qualifications of the employee under an applicable DOT agency safety regulation, a SAP evaluating the employee as part of the return to duty process (see §40.293(g)), a DOT agency, or the National Transportation Safety Board in the course of an accident investigation.

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

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

(a) As an MRO or service agent you must provide, within 10 business days of receiving a written request from an employee, copies of any records pertaining to the employee's use of alcohol and/or drugs, including records of the employee's DOT-mandated drug and/or alcohol tests. You may charge no more than the cost of preparation and reproduction for copies of these records.

(b) As a laboratory, you must provide, within 10 business days of receiving a written request from an employee, and made through the MRO, the records relating to the results of the employee's drug test (i.e., laboratory report and data package). You may charge no more than the cost of preparation and reproduction for copies of these records.

(c) As a SAP, you must make available to an employee, on request, a copy of all SAP reports (see §40.311). However, you must redact follow-up testing information from the report before providing it to the employee.

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

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

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

(a) If you receive a specific, written consent from an employee authorizing the release of information about that employee's drug or alcohol tests to an identified person, you must provide the information to the identified person. For example, as an employer, when you receive a written request from a former employee to provide information to a subsequent employer, you must do so. In providing the information, you must comply with the terms of the employee's consent.

(b) If you are an employer, you must, upon request of DOT agency representatives, provide the following:

(1) Access to your facilities used for this part and DOT agency drug and alcohol program functions.

(2) All written, printed, and computer-based drug and alcohol program records and reports (including copies of name-specific records or reports), files, materials, data, documents/documentation, agreements, contracts, policies, and statements that are required by this part and DOT agency regulations. You must provide this information at your principal place of business in the time required by the DOT agency.

(3) All items in paragraph (b)(2) of this section must be easily accessible, legible, and provided in an organized manner. If electronic records do not meet these standards, they must be converted to printed documentation that meets these standards.

(c) If you are a service agent, you must, upon request of DOT agency representatives, provide the following:

(1) Access to your facilities used for this part and DOT agency drug and alcohol program functions.

(2) All written, printed, and computer-based drug and alcohol program records and reports (including copies of name-specific records or reports), files, materials, data, documents/documentation, agreements, contracts, policies, and statements that are required by this part and DOT agency regulations. You must provide this information at your principal place of business in the time required by the DOT agency.

(3) All items in paragraph (c)(2) of this section must be easily accessible, legible, and provided in an organized manner. If electronic records do not meet these standards, they must be converted to printed documentation that meets these standards.

(d) If requested by the National Transportation Safety Board as part of an accident investigation, you must provide information concerning post-accident tests administered after the accident.

(e) If requested by a Federal, state or local safety agency with regulatory authority over you or the employee, you must provide drug and alcohol test records concerning the employee.

(f) Except as otherwise provided in this part, as a laboratory you must not release or provide a specimen or a part of a specimen to a requesting party, without first obtaining written consent from ODAPC. If a party seeks a court order directing you to release a specimen or part of a specimen contrary to any provision of this part, you must take necessary legal steps to contest the issuance of the order (e.g., seek to quash a subpoena, citing the requirements of §40.13). This part does not require you to disobey a court order, however.

(g) Notwithstanding any other provision of this Part, as an employer of Commercial Motor Vehicle (CMV) drivers holding commercial driving licenses (CDLs) or as a third party administrator for owner-operator CMV drivers with CDLs, you are authorized to comply with State laws requiring you to provide to State CDL licensing authorities information about all violations of DOT drug and alcohol testing rules (including positive tests and refusals) by any CMV driver holding a CDL.

[65 FR 79526, Dec. 19, 2000, as amended at 66 FR 41955, Aug. 9, 2001; 73 FR 33737, June 13, 2008; 75 8524, February 25, 2010]

§ 40.333 What records must employers keep?

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

(1) You must keep the following records for five years:

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

(ii) Records of verified positive drug test results;

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

(iv) SAP reports; and

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

(2) You must keep records for three years of information obtained from previous employers under §40.25 concerning drug and alcohol test results of employees.

(3) You must keep records of the inspection, maintenance, and calibration of EBTs, for two years.

(4) You must keep records of negative and cancelled drug test results and alcohol test results with a concentration of less than 0.02 for one year.

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

(c) You must maintain the records in a location with controlled access.

(d) A service agent may maintain these records for you. However, you must ensure that you can produce these records at your principal place of business in the time required by the DOT agency. For example, as a motor carrier, when an FMCSA inspector requests your records, you must ensure that you can provide them within two business days.

(e) If you store records electronically, where permitted by this part, you must ensure that the records are easily accessible, legible, and formatted and stored in an organized manner. If electronic records do not meet

these criteria, you must convert them to printed documentation in a rapid and readily auditable manner, at the request of DOT agency personnel.
[65 FR 79526, Dec. 19, 2000, as amended at 66 FR 41955, Aug. 9, 2001]

Subpart Q - Roles and Responsibilities of Service Agents

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

(a) As a service agent, the services you provide to transportation employers must meet the requirements of this part and the DOT agency drug and alcohol testing regulations.

(b) If you do not comply, DOT may take action under the Public Interest Exclusions procedures of this part (see Subpart R of this part) or applicable provisions of other DOT agency regulations.

§ 40.343 What tasks may a service agent perform for an employer?

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

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

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

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

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

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

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

(a) You may operate random testing programs for employers and may assist (i.e., through contracting with laboratories or collection sites, conducting collections) employers with other types of testing (e.g., pre-employment, post-accident, reasonable suspicion, return-to-duty, and follow-up).

(b) You may combine employees from more than one employer or one transportation industry in a random pool if permitted by all the DOT agency drug and alcohol testing regulations involved.

(1) If you combine employees from more than one transportation industry, you must ensure that the random testing rate is at least equal to the highest rate required by each DOT agency.

(2) Employees not covered by DOT agency regulations may not be part of the same random pool with DOT covered employees.

(c) You may assist employers in ensuring that follow-up testing is conducted in accordance with the plan established by the SAP. However, neither you nor the employer are permitted to randomly select employees from a "follow-up pool" for follow-up testing.

§ 40.349 What records may a service agent receive and maintain?

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

(b) You may maintain all information needed for operating a drug/alcohol program (e.g., CCFs, ATFs, names of employees in random pools, random selection lists, copies of notices to employers of selected employees) on behalf of an employer.

(c) If a service agent originating drug or alcohol testing information, such as an MRO or BAT, sends the information directly to the DER, he or she may also provide the information simultaneously to you, as a C/TPA or other service agent who maintains this information for the employer.

(d) If you are serving as an intermediary in transmitting information that is required to be provided to the employer, you must ensure that it reaches the employer in the same time periods required elsewhere in this part.

(e) You must ensure that you can make available to the employer within two business days any information the employer is asked to produce by a DOT agency representative.

(f) On request of an employer, you must, at any time on the request of an employer, transfer immediately all records pertaining to the employer and its employees to the employer or to any other service agent the employer designates. You must carry out this transfer as soon as the employer requests it. You are not required to obtain employee consent for this transfer. You must not charge more than your reasonable administrative costs for conducting this transfer. You may not charge a fee for the release of these records.

(g) If you are planning to go out of business or your organization will be bought by or merged with another organization, you must immediately notify all employers and offer to transfer all records pertaining to the employer and its employees to the employer or to any other service agent the employer designates. You must carry out this transfer as soon as the employer requests it. You are not required to obtain employee consent for this transfer. You must not charge more than your reasonable administrative costs for conducting this transfer. You may not charge a fee for the release of these records.

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

§ 40.351 What confidentiality requirements apply to service agents?

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

(a) When you receive or maintain confidential information about employees (e.g., individual test results), you must follow the same confidentiality regulations as the employer with respect to the use and release of this information.

(b) You must follow all confidentiality and records retention requirements applicable to employers.

(c) You may not provide individual test results or other confidential information to another employer without a specific, written consent from the employee. For example, suppose you are a C/TPA that has employers X and Y as clients. Employee Jones works for X, and you maintain Jones' drug and alcohol test for X. Jones wants to change jobs and work for Y. You may not inform Y of the result of a test conducted for X without having a specific, written consent from Jones. Likewise, you may not provide this information to employer Z, who is not a C/TPA member, without this consent.

(d) You must not use blanket consent forms authorizing the release of employee testing information.

(e) You must establish adequate confidentiality and security measures to ensure that confidential employee records are not available to unauthorized persons. This includes protecting the physical security of records, access controls, and computer security measures to safeguard confidential data in electronic data bases.

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

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

(a) You may provide MRO services to employers, directly or through contract, if you meet all applicable provisions of this part.

(b) If you employ or contract for an MRO, the MRO must perform duties independently and confidentially. When you have a relationship with an MRO, you must structure the relationship to ensure that this independence and confidentiality are not compromised. Specific means (including both physical and operational measures, as appropriate) to separate MRO functions and other service agent functions are essential.

(c) Only your staff who are actually under the day-to-day supervision and control of an MRO with respect to MRO functions may perform these functions. This does not mean that those staff may not perform other functions at other times. However, the designation of your staff to perform MRO functions under MRO supervision must be limited and not used as a subterfuge to circumvent confidentiality and other requirements of this part and DOT agency regulations. You must ensure that MRO staff operate under controls sufficient to ensure that the independence and confidentiality of the MRO process are not compromised.

(d) Like other MROs, an MRO you employ or contract with must personally conduct verification interviews with employees and must personally make all verification decisions. Consequently, your staff cannot perform these functions.

§ 40.355 What limitations apply to the activities of service agents?

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

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

(b) You must not act as an intermediary in the transmission of drug test results from the laboratory to the MRO. That is, the laboratory may not send results to you, with you in turn sending them to the MRO for verification. For example, a practice in which the laboratory transmits results to your computer system, and you then assign the results to a particular MRO, is not permitted.

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

(d) You must not act as an intermediary in the transmission of alcohol test results of 0.02 or higher from the STT or BAT to the DER.

(e) Except as provided in paragraph (f) of this section, you must not act as an intermediary in the transmission of individual SAP reports to the actual employer. That is, the SAP may not send such reports to you, with you in turn sending them to the actual employer. However, you may maintain individual SAP summary reports and follow-up testing plans after they are sent to the DER, and the SAP may transmit such reports to you simultaneously with sending them to the DER.

(f) As an exception to paragraph (e) of this section, you may act as an intermediary in the transmission of SAP report from the SAP to an owner-operator or other self-employed individual.

(g) Except as provided in paragraph (h) of this section, you must not make decisions to test an employee based upon reasonable suspicion, post-accident, return-to-duty, and follow-up determination criteria. These are duties the actual employer cannot delegate to a C/TPA. You may, however, provide advice and information to employers regarding these testing issues and how the employer should schedule required testing.

(h) As an exception to paragraph (g) of this section, you may make decisions to test an employee based upon reasonable suspicion, post-accident, return-to-duty, and follow-up determination criteria with respect to an owner-operator or other self-employed individual.

(i) Except as provided in paragraph (j) of this section, you must not make a determination that an employee has refused a drug or alcohol test. This is a non-delegable duty of the actual employer. You may, however, provide advice and information to employers regarding refusal-to-test issues.

(j) As an exception to paragraph (i) of this section, you may make a determination that an employee has refused a drug or alcohol test, if:

(1) You schedule a required test for an owner-operator or other self-employed individual, and the individual fails to appear for the test without a legitimate reason; or

(2) As an MRO, you determine that an individual has refused to test on the basis of adulteration or substitution.

(k) You must not act as a DER. For example, while you may be responsible for transmitting information to the employer about test results, you must not act on behalf of the employer in actions to remove employees from safety-sensitive duties.

(l) In transmitting documents to laboratories, you must ensure that you send to the laboratory that conducts testing only the laboratory copy of the CCF. You must not transmit other copies of the CCF or any ATFs to the laboratory.

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

(n) You must not intentionally delay the transmission of drug or alcohol testing-related documents concerning actions you have performed, because of a payment dispute or other reasons.

Example 1 to Paragraph (n): A laboratory that has tested a specimen must not delay transmitting the documentation of the test result to an MRO because of a billing or payment dispute with the MRO or a C/TPA.

Example 2 to Paragraph (n): An MRO or SAP who has interviewed an employee must not delay sending a verified test result or SAP report to the employer because of such a dispute with the employer or employee.

Example 3 to Paragraph (n): A collector who has performed a urine specimen collection must not delay sending the drug specimen and CCF to the laboratory because of a payment or other dispute with the laboratory or a C/TPA.

Example 4 to Paragraph (n): A BAT who has conducted an alcohol test must not delay sending test result information to an employer or C/TPA because of a payment or other dispute with the employer or C/TPA.

(o) While you must follow the DOT agency regulations, the actual employer remains accountable to DOT for compliance, and your failure to implement any aspect of the program as required in this part and other applicable DOT agency regulations makes the employer subject to enforcement action by the Department.
[65 FR 79526, Dec. 19, 2000, as amended at 66 FR 41955, Aug. 9, 2001]

Subpart R - Public Interest Exclusions

§ 40.361 What is the purpose of a public interest exclusion (PIE)?

(a) To protect the public interest, including protecting transportation employers and employees from serious noncompliance with DOT drug and alcohol testing rules, the Department's policy is to ensure that employers conduct business only with responsible service agents.

(b) The Department therefore uses PIEs to exclude from participation in DOT's drug and alcohol testing program any service agent who, by serious noncompliance with this part or other DOT agency drug and alcohol testing regulations, has shown that it is not currently acting in a responsible manner.

(c) A PIE is a serious action that the Department takes only to protect the public interest. We intend to use PIEs only to remedy situations of serious noncompliance. PIEs are not used for the purpose of punishment.

(d) Nothing in this subpart precludes a DOT agency or the Inspector General from taking other action authorized by its regulations with respect to service agents or employers that violate its regulations.

§ 40.363 On what basis may the Department issue a PIE?

(a) If you are a service agent, the Department may issue a PIE concerning you if we determine that you have failed or refused to provide drug or alcohol testing services consistent with the requirements of this part or a DOT agency drug and alcohol regulation.

(b) The Department also may issue a PIE if you have failed to cooperate with DOT agency representatives concerning inspections, complaint investigations, compliance and enforcement reviews, or

requests for documents and other information about compliance with this part or DOT agency drug and alcohol regulations.

§ 40.365 What is the Department's policy concerning starting a PIE proceeding?

(a) It is the Department's policy to start a PIE proceeding only in cases of serious, uncorrected noncompliance with the provisions of this part, affecting such matters as safety, the outcomes of test results, privacy and confidentiality, due process and fairness for employees, the honesty and integrity of the testing program, and cooperation with or provision of information to DOT agency representatives.

(b) The following are examples of the kinds of serious noncompliance that, as a matter of policy, the Department views as appropriate grounds for starting a PIE proceeding. These examples are not intended to be an exhaustive or exclusive list of the grounds for starting a PIE proceeding. We intend them to illustrate the level of seriousness that the Department believes supports starting a PIE proceeding. The examples follow:

(1) For an MRO, verifying tests positive without interviewing the employees as required by this part or providing MRO services without meeting the qualifications for an MRO required by this part;

(2) For a laboratory, refusing to provide information to the Department, an employer, or an employee as required by this part; failing or refusing to conduct a validity testing program when required by this part; or a pattern or practice of testing errors that result in the cancellation of tests. (As a general matter of policy, the Department does not intend to initiate a PIE proceeding concerning a laboratory with respect to matters on which HHS initiates certification actions under its laboratory guidelines.);

(3) For a collector, a pattern or practice of directly observing collections when doing so is unauthorized, or failing or refusing to directly observe collections when doing so is mandatory;

(4) For collectors, BATs, or STTs, a pattern or practice of using forms, testing equipment, or collection kits that do not meet the standards in this part;

(5) For a collector, BAT, or STT, a pattern or practice of "fatal flaws" or other significant uncorrected errors in the collection process;

(6) For a laboratory, MRO or C/TPA, failing or refusing to report tests results as required by this part or DOT agency regulations;

(7) For a laboratory, falsifying, concealing, or destroying documentation concerning any part of the drug testing process, including, but not limited to, documents in a "litigation package";

(8) For SAPs, providing SAP services while not meeting SAP qualifications required by this part or performing evaluations without face-to-face interviews;

(9) For any service agent, maintaining a relationship with another party that constitutes a conflict of interest under this part (e.g., a laboratory that derives a financial benefit from having an employer use a specific MRO);

(10) For any service agent, representing falsely that the service agent or its activities is approved or certified by the Department or a DOT agency;

(11) For any service agent, disclosing an employee's test result information to any party this part or a DOT agency regulation does not authorize, including by obtaining a "blanket" consent from employees or by creating a data base from which employers or others can retrieve an employee's DOT test results without the specific consent of the employee;

(12) For any service agent, interfering or attempting to interfere with the ability of an MRO to communicate with the Department, or retaliating against an MRO for communicating with the Department;

(13) For any service agent, directing or recommending that an employer fail or refuse to implement any provision of this part; or

(14) With respect to noncompliance with a DOT agency regulation, conduct that affects important provisions of Department-wide concern (e.g., failure to properly conduct the selection process for random testing).

§ 40.367 Who initiates a PIE proceeding?

The following DOT officials may initiate a PIE proceeding:

(a) The drug and alcohol program manager of a DOT agency;

(b) An official of ODAPC, other than the Director; or

(c) The designee of any of these officials.

§ 40.369 What is the discretion of an initiating official in starting a PIE proceeding?

(a) Initiating officials have broad discretion in deciding whether to start a PIE proceeding.

(b) In exercising this discretion, the initiating official must consider the Department's policy regarding the seriousness of the service agent's conduct (see §40.365) and all information he or she has obtained to this point concerning the facts of the case. The initiating official may also consider the availability of the resources needed to pursue a PIE proceeding.

(c) A decision not to initiate a PIE proceeding does not necessarily mean that the Department regards a service agent as being in compliance or that the Department may not use other applicable remedies in a situation of noncompliance.

§ 40.371 On what information does an initiating official rely in deciding whether to start a PIE proceeding?

(a) An initiating official may rely on credible information from any source as the basis for starting a PIE proceeding.

(b) Before sending a correction notice (see §40.373), the initiating official informally contacts the service agent to determine if there is any information that may affect the initiating official's determination about whether it is necessary to send a correction notice. The initiating official may take any information resulting from this contact into account in determining whether to proceed under this subpart.

§ 40.373 Before starting a PIE proceeding, does the initiating official give the service agent an opportunity to correct problems?

(a) If you are a service agent, the initiating official must send you a correction notice before starting a PIE proceeding.

(b) The correction notice identifies the specific areas in which you must come into compliance in order to avoid being subject to a PIE proceeding.

(c) If you make and document changes needed to come into compliance in the areas listed in the correction notice to the satisfaction of the initiating official within 60 days of the date you receive the notice, the initiating official does not start a PIE proceeding. The initiating official may conduct appropriate fact finding to verify that you have made and maintained satisfactory corrections. When he or she is satisfied that you are in compliance, the initiating official sends you a notice that the matter is concluded.

§ 40.375 How does the initiating official start a PIE proceeding?

(a) As a service agent, if your compliance matter is not correctable (see §40.373(a)), or if have not resolved compliance matters as provided in §40.373(c), the initiating official starts a PIE proceeding by sending you a notice of proposed exclusion (NOPE). The NOPE contains the initiating official's recommendations concerning the issuance of a PIE, but it is not a decision by the Department to issue a PIE.

(b) The NOPE includes the following information:

(1) A statement that the initiating official is recommending that the Department issue a PIE concerning you;

(2) The factual basis for the initiating official's belief that you are not providing drug and/or alcohol testing services to DOT-regulated employers consistent with the requirements of this part or are in serious noncompliance with a DOT agency drug and alcohol regulation;

(3) The factual basis for the initiating official's belief that your noncompliance has not been or cannot be corrected;

(4) The initiating official's recommendation for the scope of the PIE;

(5) The initiating official's recommendation for the duration of the PIE; and

(6) A statement that you may contest the issuance of the proposed PIE, as provided in §40.379.

(c) The initiating official sends a copy of the NOPE to the ODAPC Director at the same time he or she sends the NOPE to you.

§ 40.377 Who decides whether to issue a PIE?

(a) The ODAPC Director, or his or her designee, decides whether to issue a PIE. If a designee is acting as the decisionmaker, all references in this subpart to the Director refer to the designee.

(b) To ensure his or her impartiality, the Director plays no role in the initiating official's determination about whether to start a PIE proceeding.

(c) There is a "firewall" between the initiating official and the Director. This means that the initiating official and the Director are prohibited from having any discussion, contact, or exchange of information with one another about the matter, except for documents and discussions that are part of the record of the proceeding.

§ 40.379 How do you contest the issuance of a PIE?

(a) If you receive a NOPE, you may contest the issuance of the PIE.

(b) If you want to contest the proposed PIE, you must provide the Director information and argument in opposition to the proposed PIE in writing, in person, and/or through a representative. To contest the proposed PIE, you must take one or more of the steps listed in this paragraph (b) within 30 days after you receive the NOPE.

(1) You may request that the Director dismiss the proposed PIE without further proceedings, on the basis that it does not concern serious noncompliance with this part or DOT agency regulations, consistent with the Department's policy as stated in §40.365.

(2) You may present written information and arguments, consistent with the provisions of §40.381, contesting the proposed PIE.

(3) You may arrange with the Director for an informal meeting to present your information and arguments.

(c) If you do not take any of the actions listed in paragraph (b) of this section within 30 days after you receive the NOPE, the matter proceeds as an uncontested case. In this event, the Director makes his or her decision based on the record provided by the initiating official (i.e., the NOPE and any supporting information or testimony) and any additional information the Director obtains.

§ 40.381 What information do you present to contest the proposed issuance of a PIE?

(a) As a service agent who wants to contest a proposed PIE, you must present at least the following information to the Director:

(1) Specific facts that contradict the statements contained in the NOPE (see §40.375(b)(2) and (3)). A general denial is insufficient to raise a genuine dispute over facts material to the issuance of a PIE;

(2) Identification of any existing, proposed or prior PIE; and

(3) Identification of your affiliates, if any.

(b) You may provide any information and arguments you wish concerning the proposed issuance, scope and duration of the PIE (see §40.375(b)(4) and (5)).

(c) You may provide any additional relevant information or arguments concerning any of the issues in the matter.

§ 40.383 What procedures apply if you contest the issuance of a PIE?

(a) DOT conducts PIE proceedings in a fair and informal manner. The Director may use flexible procedures to allow you to present matters in opposition. The Director is not required to follow formal rules of evidence or procedure in creating the record of the proceeding.

(b) The Director will consider any information or argument he or she determines to be relevant to the decision on the matter.

(c) You may submit any documentary evidence you want the Director to consider. In addition, if you have arranged an informal meeting with the Director, you may present witnesses and confront any person the initiating official presents as a witness against you.

(d) In cases where there are material factual issues in dispute, the Director or his or her designee may conduct additional fact-finding.

(e) If you have arranged a meeting with the Director, the Director will make a transcribed record of the meeting available to you on your request. You must pay the cost of transcribing and copying the meeting record.

§ 40.385 Who bears the burden of proof in a PIE proceeding?

(a) As the proponent of issuing a PIE, the initiating official bears the burden of proof.

(b) This burden is to demonstrate, by a preponderance of the evidence, that the service agent was in serious noncompliance with the requirements of this part for drug and/or alcohol testing-related services or with the requirements of another DOT agency drug and alcohol testing regulation.

§ 40.387 What matters does the Director decide concerning a proposed PIE?

(a) Following the service agent's response (see §40.379(b)) or, if no response is received, after 30 days have passed from the date on which the service agent received the NOPE, the Director may take one of the following steps:

(1) In response to a request from the service agent (see §40.379(b)(1)) or on his or her own motion, the Director may dismiss a PIE proceeding if he or she determines that it does not concern serious noncompliance with this part or DOT agency regulations, consistent with the Department's policy as stated in §40.365.

(i) If the Director dismisses a proposed PIE under this paragraph (a), the action is closed with respect to the noncompliance alleged in the NOPE.

(ii) The Department may initiate a new PIE proceeding against you on the basis of different or subsequent conduct that is in noncompliance with this part or other DOT drug and alcohol testing rules.

(2) If the Director determines that the initiating official's submission does not have complete information needed for a decision, the Director may remand the matter to the initiating official. The initiating official may resubmit the matter to the Director when the needed information is complete. If the basis for the proposed PIE has changed, the initiating official must send an amended NOPE to the service agent.

(b) The Director makes determinations concerning the following matters in any PIE proceeding that he or she decides on the merits:

(1) Any material facts that are in dispute;

(2) Whether the facts support issuing a PIE;

(3) The scope of any PIE that is issued; and

(4) The duration of any PIE that is issued.

§ 40.389 What factors may the Director consider?

This section lists examples of the kind of mitigating and aggravating factors that the Director may consider in determining whether to issue a PIE concerning you, as well as the scope and duration of a PIE. This list is not exhaustive or exclusive. The Director may consider other factors if appropriate in the circumstances of a particular case. The list of examples follows:

(a) The actual or potential harm that results or may result from your noncompliance;

(b) The frequency of incidents and/or duration of the noncompliance;

(c) Whether there is a pattern or prior history of noncompliance;

(d) Whether the noncompliance was pervasive within your organization, including such factors as the following:

(1) Whether and to what extent your organization planned, initiated, or carried out the noncompliance;

(2) The positions held by individuals involved in the noncompliance, and whether your principals tolerated their noncompliance; and

(3) Whether you had effective standards of conduct and control systems (both with respect to your own organization and any contractors or affiliates) at the time the noncompliance occurred;

(e) Whether you have demonstrated an appropriate compliance disposition, including such factors as the following:

(1) Whether you have accepted responsibility for the noncompliance and recognize the seriousness of the conduct that led to the cause for issuance of the PIE;

(2) Whether you have cooperated fully with the Department during the investigation. The Director may consider when the cooperation began and whether you disclosed all pertinent information known to you;

(3) Whether you have fully investigated the circumstances of the noncompliance forming the basis for the PIE and, if so, have made the result of the investigation available to the Director;

(4) Whether you have taken appropriate disciplinary action against the individuals responsible for the activity that constitutes the grounds for issuance of the PIE; and

(5) Whether your organization has taken appropriate corrective actions or remedial measures, including implementing actions to prevent recurrence;

(f) With respect to noncompliance with a DOT agency regulation, the degree to which the noncompliance affects matters common to the DOT drug and alcohol testing program;

(g) Other factors appropriate to the circumstances of the case.

§ 40.391 What is the scope of a PIE?

(a) The scope of a PIE is the Department's determination about the divisions, organizational elements, types of services, affiliates, and/or individuals (including direct employees of a service agent and its contractors) to which a PIE applies.

(b) If, as a service agent, the Department issues a PIE concerning you, the PIE applies to all your divisions, organizational elements, and types of services that are involved with or affected by the noncompliance that forms the factual basis for issuing the PIE.

(c) In the NOPE (see §40.375(b)(4)), the initiating official sets forth his or her recommendation for the scope of the PIE. The proposed scope of the PIE is one of the elements of the proceeding that the service agent may contest (see §40.381(b)) and about which the Director makes a decision (see §40.387(b)(3)).

(d) In recommending and deciding the scope of the PIE, the initiating official and Director, respectively, must take into account the provisions of paragraphs (e) through (j) of this section.

(e) The pervasiveness of the noncompliance within a service agent's organization (see §40.389(d)) is an important consideration in determining the scope of a PIE. The appropriate scope of a PIE grows broader as the pervasiveness of the noncompliance increases.

(f) The application of a PIE is not limited to the specific location or employer at which the conduct that forms the factual basis for issuing the PIE was discovered.

(g) A PIE applies to your affiliates, if the affiliate is involved with or affected by the conduct that forms the factual basis for issuing the PIE.

(h) A PIE applies to individuals who are officers, employees, directors, shareholders, partners, or other individuals associated with your organization in the following circumstances:

(1) Conduct forming any part of the factual basis of the PIE occurred in connection with the individual's performance of duties by or on behalf of your organization; or

(2) The individual knew of, had reason to know of, approved, or acquiesced in such conduct. The individual's acceptance of benefits derived from such conduct is evidence of such knowledge, acquiescence, or approval.

(i) If a contractor to your organization is solely responsible for the conduct that forms the factual basis for a PIE, the PIE does not apply to the service agent itself unless the service agent knew or should have known about the conduct and did not take action to correct it.

(j) PIEs do not apply to drug and alcohol testing that DOT does not regulate.

(k) The following examples illustrate how the Department intends the provisions of this section to work:

Example 1 to §40.391. Service Agent P provides a variety of drug testing services. P's SAP services are involved in a serious violation of this Part 40. However, P's other services fully comply with this part, and P's overall management did not plan or concur in the noncompliance, which in fact was contrary to P's articulated standards. Because the noncompliance was isolated in one area of the organization's activities, and did not pervade the entire organization, the scope of the PIE could be limited to SAP services.

Example 2 to §40.391. Service Agent Q provides a similar variety of services. The conduct forming the factual basis for a PIE concerns collections for a transit authority. As in Example 1, the noncompliance is not pervasive throughout Q's organization. The PIE would apply to collections at all locations served by Q, not just the particular transit authority or not just in the state in which the transit authority is located.

Example 3 to §40.391. Service Agent R provides a similar array of services. One or more of the following problems exists: R's activities in several areas—collections, MROs, SAPs, protecting the confidentiality of information—are involved in serious noncompliance; DOT determines that R's management knew or should have known about serious noncompliance in one or more areas, but management did not take timely corrective action; or, in response to an inquiry from DOT personnel, R's management refuses to provide information about its operations. In each of these three cases, the scope of the PIE would include all aspects of R's services.

Example 4 to §40.391. Service Agent W provides only one kind of service (e.g., laboratory or MRO services). The Department issues a PIE concerning these services. Because W only provides this one kind of service, the PIE necessarily applies to all its operations.

Example 5 to §40.391. Service Agent X, by exercising reasonably prudent oversight of its collection contractor, should have known that the contractor was making numerous "fatal flaws" in tests. Alternatively, X received a correction notice pointing out these problems in its contractor's collections. In neither case did X take action to correct the problem. X, as well as the contractor, would be subject to a PIE with respect to collections.

Example 6 to §40.391. Service Agent Y could not reasonably have known that one of its MROs was regularly failing to interview employees before verifying tests positive. When it received a correction notice, Y immediately dismissed the erring MRO. In this case, the MRO would be subject to a PIE but Y would not.

Example 7 to §40.391. The Department issues a PIE with respect to Service Agent Z. Z provides services for DOT-regulated transportation employers, a Federal agency under the HHS-regulated Federal employee testing program, and various private businesses and public agencies that DOT does not regulate. The PIE applies only to the DOT-regulated transportation employers with respect to their DOT-mandated testing, not to the Federal agency or the other public agencies and private businesses. The PIE does not prevent the non-DOT regulated entities from continuing to use Z's services.

§ 40.393 How long does a PIE stay in effect?

(a) In the NOPE (see §40.375(b)(5)), the initiating official proposes the duration of the PIE. The duration of the PIE is one of the elements of the proceeding that the service agent may contest (see §40.381(b)) and about which the Director makes a decision (see §40.387(b)(4)).

(b) In deciding upon the duration of the PIE, the Director considers the seriousness of the conduct on which the PIE is based and the continued need to protect employers and employees from the service agent's noncompliance. The Director considers factors such as those listed in §40.389 in making this decision.

c) The duration of a PIE will be between one and five years, unless the Director reduces its duration under §40.407.

§ 40.395 Can you settle a PIE proceeding?

any time before the Director's decision, you and the initiating official can, with the Director's concurrence, settle a PIE proceeding.

§ 40.397 When does the Director make a PIE decision?

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.

§ 40.399 How does the Department notify service agents of its decision?

you are a service agent involved in a PIE proceeding, the Director provides you written notice as soon as he or she makes a PIE decision. The notice includes the following elements:

(a) If the decision is not to issue a PIE, a statement of the reasons for the decision, including findings of fact with respect to any material factual issues that were in dispute.

(b) If the decision is to issue a PIE—

(1) A reference to the NOPE;

(2) A statement of the reasons for the decision, including findings of fact with respect to any material factual issues that were in dispute;

(3) A statement of the scope of the PIE; and

(4) A statement of the duration of the PIE.

§ 40.401 How does the Department notify employers and the public about a PIE?

(a) The Department maintains a document called the "List of Excluded Drug and Alcohol Service Agents." This document may be found on the Department's web site (http://www.dot.gov/ost/dapc). You may also request a copy of the document from ODAPC.

(b) When the Director issues a PIE, he or she adds to the List the name and address of the service agent, and any other persons or organizations, to whom the PIE applies and information about the scope and duration of the PIE.

(c) When a service agent ceases to be subject to a PIE, the Director removes this information from the List.

(d) The Department also publishes a Federal Register notice to inform the public on any occasion on which a service agent is added to or taken off the List.

§ 40.403 Must a service agent notify its clients when the Department issues a PIE?

(a) As a service agent, if the Department issues a PIE concerning you, you must notify each of your DOT-regulated employer clients, in writing, about the issuance, scope, duration, and effect of the PIE. You may meet this requirement by sending a copy of the Director's PIE decision or by a separate notice. You must send this notice to each client within three business days of receiving from the Department the notice provided for in §40.399(b).

(b) As part of the notice you send under paragraph (a) of this section, you must offer to transfer immediately all records pertaining to the employer and its employees to the employer or to any other service agent the employer designates. You must carry out this transfer as soon as the employer requests it.
[65 FR 79526, Dec. 19, 2000, as amended at 66 FR 41955, Aug. 9, 2001]

§ 40.405 May the Federal courts review PIE decisions?

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).

§ 40.407 May a service agent ask to have a PIE reduced or terminated?

(a) Yes, as a service agent concerning whom the Department has issued a PIE, you may request that the Director terminate a PIE or reduce its duration and/or scope. This process is limited to the issues of duration and scope. It is not an appeal or reconsideration of the decision to issue the PIE.

(b) Your request must be in writing and supported with documentation.

(c) You must wait at least nine months from the date on which the Director issued the PIE to make this request.

(d) The initiating official who was the proponent of the PIE may provide information and arguments concerning your request to the Director.

(e) If the Director verifies that the sources of your noncompliance have been eliminated and that all drug or
alcohol testing-related services you would provide to DOT-regulated employers will be consistent with the requirements of this part, the Director may issue a notice terminating or reducing the PIE.

§ 40.409 What does the issuance of a PIE mean to transportation employers?

(a) As an employer, you are deemed to have notice of the issuance of a PIE when it appears on the List mentioned in §40.401(a) or the notice of the PIE appears in the Federal Register as provided in §40.401(d). You should check this List to ensure that any service agents you are using or planning to use are not subject to a PIE.

(b) As an employer who is using a service agent concerning whom a PIE is issued, you must s using the services of the service agent no later than 90 days after the Department has published the decision in the Federal Register or posted it on its web site. You may apply to the ODAPC Director for an extension of 30 days if you demonstrate that you cannot find a substitute service agent within 90 days.

(c) Except during the period provided in paragraph (b) of this section, you must not, as an employer, use the services of a service agent that are covered by a PIE that the Director has issued under this subpart. If you do so, you are in violation of the Department's regulations and subject to applicable DOT agency sanctions (e.g., civil penalties, withholding of Federal financial assistance).

(d) You also must not obtain drug or alcohol testing services through a contractor or affiliate of the service agent to whom the PIE applies.

Example to Paragraph (d): Service Agent R was subject to a PIE with respect to SAP services. As an employer, not only must you not use R's own SAP services, but you also must not use SAP services you arrange through R, such as services provided by a subcontractor or affiliate of R or a person or organization that receives financial gain from its relationship with R.

(e) This section's prohibition on using the services of a service agent concerning which the Director has issued a PIE applies to employers in all industries subject to DOT drug and alcohol testing regulations.

Example to Paragraph (e): The initiating official for a PIE was the FAA drug and alcohol program manager, and the conduct forming the basis of the PIE pertained to the aviation industry. As a motor carrier, transit authority, pipeline, railroad, or maritime employer, you are also prohibited from using the services of the service agent involved in connection with the DOT drug and alcohol testing program.

(f) The issuance of a PIE does not result in the cancellation of drug or alcohol tests conducted using the service agent involved before the issuance of the Director's decision or up to 90 days following its publication in the Federal Register or posting on the Department's web site, unless otherwise specified in the Director's PIE decision or the Director grants an extension as provided in paragraph (b) of this section.

Example to Paragraph (f): The Department issues a PIE concerning Service Agent N on September 1. All tests conducted using N's services before September 1, and through November 30, are valid for all purposes under DOT drug and alcohol testing regulations, assuming they meet all other regulatory requirements.

§ 40.411 What is the role of the DOT Inspector General's office?

(a) Any person may bring concerns about waste, fraud, or abuse on the part of a service agent to the attention of the DOT Office of Inspector General.

(b) In appropriate cases, the Office of Inspector General may pursue criminal or civil remedies against a service agent.

(c) The Office of Inspector General may provide factual information to other DOT officials for use in a PIE proceeding.

§ 40.413 How are notices sent to service agents?

(a) If you are a service agent, DOT sends notices to you, including correction notices, notices of proposed exclusion, decision notices, and other notices, in any of the ways mentioned in paragraph (b) or (c) of this section.

(b) DOT may send a notice to you, your identified counsel, your agent for service of process, or any of your partners, officers, directors, owners, or joint venturers to the last known street address, fax number, or e-mail address. DOT deems the notice to have been received by you if sent to any of these persons.

(c) DOT considers notices to be received by you—

(1) When delivered, if DOT mails the notice to the last known street address, or five days after we send it if the letter is undeliverable;

(2) When sent, if DOT sends the notice by fax or five days after we send it if the fax is undeliverable; or

(3) When delivered, if DOT sends the notice by e-mail or five days after DOT sends it if the e-mail is undeliverable.

Appendix A to Part 40 - DOT Standards for Urine Collection Kits

The Collection Kit Contents

1. Collection Container

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

b. Must have graduated volume markings clearly noting levels of 45 mL and above.

c. Must have a temperature strip providing graduated temperature readings 32–38 °C/90–100 °F, that is affixed or can be affixed at a proper level on the outside of the collection container. Other methodologies (e.g., temperature device built into the wall of the container) are acceptable provided the temperature measurement is accurate and such that there is no potential for contamination of the specimen.

d. Must be individually wrapped in a sealed plastic bag or shrink wrapping; or must have a peelable, sealed lid or other easily visible tamper-evident system.

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

2. Plastic Specimen Bottles

a. Each bottle must be large enough to hold at least 35 mL; or alternatively, they may be two distinct sizes of specimen bottles provided that the bottle designed to hold the primary specimen holds at least 35 mL of urine and the bottle designed to hold the split specimen holds at least 20 mL.

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

c. Must have markings clearly indicating the appropriate levels (30 mL for the primary specimen and 15 mL for the split) of urine that must be poured into the bottles.

d. Must be designed so that the required tamper-evident bottle seals made available on the CCF fit with no damage to the seal when the employee initials it nor with the chance that the seal overlap would conceal printed information.

e. Must be wrapped (with caps) together in a sealed plastic bag or shrink wrapping separate from the collection container; or must be wrapped (with cap) individually in sealed plastic bags or shrink wrapping; or must have peelable, sealed lid or other easily visible tamper-evident system.

f. Plastic material must be leach resistant.

3. Leak-Resistant Plastic Bag

a. Must have two sealable compartments or pouches which are leak-resistant; one large enough to hold two specimen bottles and the other large enough to hold the CCF paperwork.

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

4. Absorbent material

Each kit must contain enough absorbent material to absorb the entire contents of both specimen bottles. Absorbent material must be designed to fit inside the leak-resistant plastic bag pouch into which the specimen bottles are placed.

5. Shipping Container

a. Must be designed to adequately protect the specimen bottles from shipment damage in the transport of specimens from the collection site to the laboratory (e.g., standard courier box, small cardboard box, plastic container).

b. May be made available separately at collection sites rather than being part of an actual kit sent to collection sites.

c. A shipping container is not necessary if a laboratory courier hand-delivers the specimen bottles in the plastic leak-proof bags from the collection site to the laboratory.

Appendix B to Part 40 - DOT Drug Testing Semi-Annual Laboratory Report to Employers

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. Specimen Results Reported (total number)
By Type of Test
    (a) Pre-employment (number)
    (b) Post-Accident (number)
    (c) Random (number)
    (d) Reasonable Suspicion/Cause (number)
    (e) Return-to-Duty (number)
    (f) Follow-up (number)
    (g) Type of Test Not Noted on CCF (number)

2. Specimens Reported
    (a) Negative (number)
    (b) Negative and Dilute (number)

3. Specimens Reported as Rejected for Testing (total number)
By Reason
    (a) Fatal flaw (number)
    (b) Uncorrected Flaw (number)

4. Specimens Reported as Positive (total number) By Drug
    (a) Marijuana Metabolite (number)
    (b) Cocaine Metabolite (number)
    (c) Opiates (number)
        (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 Result (number)

[65 FR 79526, Dec. 19, 2000, as amended 73 FR 35975, June 25, 2008] **Appendix C to Part 40-DOT Drug Testing Semi-Annual Laboratory Report to DOT**

Mail, fax, or email to:

U.S. Department of Transportation
Office of Drug and Alcohol Policy and Compliance
W62-300
1200 New Jersey Avenue, S.E.
Washington, DC 20590
Fax: (202) 366-3897
Email: ODAPCWebMail@dot.gov

The following items are required on each report:

Reporting Period: (inclusive dates)
Laboratory Identification: (name and address)

1. DOT Specimen Results Reported (number)

2. Negative Results Reported (number)

3. Rejected for Testing Reported (number)
   By Reason (number)

4. Positive Results Reported (number)
   By Drug (number)

5. Adulterated Results Reported (number)
   By Reason (number)

6. Substituted Results Reported (number)

7. Invalid Results Reported (number)
   By Reason (number)

[73 FR 35975, June 25, 2008]

Appendix D to Part 40 - Report Format: Split Specimen Failure to Reconfirm

Mail, fax, or submit electronically to:

U.S. Department of Transportation
Office of Drug and Alcohol Policy and Compliance
W62-300
1200 New Jersey Avenue, S.E.
Washington, DC 20590
Fax: (202) 366-3897

Submit Electronically: http://www.dot.gov/ost/dapc/mro_split.html

The following items are required on each report:

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).

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

Appendix E to Part 40 - SAP Equivalency Requirements for Certification Organizations

1. Experience: Minimum requirements are for three years of full-time supervised experience or 6,000 hours of supervised experience as an alcoholism and/or drug abuse counselor. The supervision must be provided by a licensed or certified practitioner. Supervised experience is important if the individual is to be considered a professional in the field of alcohol and drug abuse evaluation and counseling.

2. Education: There exists a requirement of 270 contact hours of education and training in alcoholism and/or drug abuse or related training. These hours can take the form of formal education, in-service training, and professional development courses. Part of any professional counselor's development is participation in formal and non-formal education opportunities within the field.

3. Continuing Education: The certified counselor must receive at least 40–60 hours of continuing education units (CEU) during each two year period. These CEUs are important to the counselor's keeping abreast of changes and improvements in the field.

4. Testing: A passing score on a national test is a requirement. The test must accurately measure the application of the knowledge, skills, and abilities possessed by the counselor. The test establishes a national standard that must be met to practice.

5. Testing Validity: The certification examination must be reviewed by an independent authority for validity (examination reliability and relationship to the knowledge, skills, and abilities required by the counseling field). The reliability of the exam is paramount if counselor attributes are to be accurately measured. The examination passing score point must be placed at an appropriate minimal level score as gauged by statistically reliable methodology.

6. Measurable Knowledge Base: The certification process must be based upon measurable knowledge possessed by the applicant and verified through collateral data and testing. That level of knowledge must be of sufficient quantity to ensure a high quality of SAP evaluation and referral services.

7. Measurable Skills Base: The certification process must be based upon measurable skills possessed by the applicant and verified through collateral data and testing. That level of skills must be of sufficient quality to ensure a high quality of SAP evaluation and referral services.

8. Quality Assurance Plan: The certification agency must ensure that a means exists to determine that applicant records are verified as being true by the certification staff. This is an important check to ensure that true information is being accepted by the certifying agency.

9. Code of Ethics: Certified counselors must pledge to adhere to an ethical standard for practice. It must be understood that code violations could result in de-certification. These standards are vital in maintaining the integrity of practitioners. High ethical standards are required to ensure quality of client care and confidentiality of client information as well as to guard against inappropriate referral practices.

10. Re-certification Program: Certification is not just a one-time event. It is a continuing privilege with continuing requirements. Among these are continuing education, continuing state certification, and concomitant adherence to the code of ethics. Re-certification serves as a protector of client interests by removing poor performers from the certified practice.

11. Fifty State Coverage: Certification must be available to qualified counselors in all 50 states and, therefore, the test must be available to qualified applicants in all 50 states. Because many companies are multi-state operators, consistency in SAP evaluation quality and opportunities is paramount. The test need not be given in all 50 states but should be accessible to candidates from all states.

12. National Commission for Certifying Agencies (NCCA) Accreditation: Having NCCA accreditation is a means of demonstrating to the Department of Transportation that your certification has been reviewed by a panel of impartial experts that have determined that your examination(s) has met stringent and appropriate testing standards.

Appendix F to Part 40 - Drug and Alcohol Testing Information that C/TPAs May Transmit to Employers

1. If you are a C/TPA, you may, acting as an intermediary, transmit the information in the following sections of this part to the DER for an employer, if the employer chooses to have you do so. These are the only items that you are permitted to transmit to the employer as an intermediary. The use of C/TPA intermediaries is prohibited in all other cases, such as transmission of laboratory drug test results to MROs, the transmission of medical information from MROs to employers, the transmission of SAP reports to employers, the transmission of positive alcohol test results, and the transmission of medical information from MROs to employers.

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

Drug Testing Information

§40.25: Previous two years' test results
§40.35: Notice to collectors of contact information for DER
§40.61(a): Notification to DER that an employee is a "no show" for a drug test
§40.63(e): Notification to DER of a collection under direct observation
§40.65(b)(6) and (7) and (c)(2) and (3): Notification to DER of a refusal to provide a specimen or an insufficient specimen
§40.73(a)(9): Transmission of CCF copies to DER (However, MRO copy of CCF must be sent by collector directly to the MRO, not through the C/TPA.)
§40.111(a): Transmission of laboratory statistical report to employer
§40.127(f): Report of test results to DER
§§40.127(g), 40.129(d), 40.159(a)(4)(ii); 40.161(b): Reports to DER that test is cancelled
§40.129 (d): Report of test results to DER
§40.129(g)(1): Report to DER of confirmed positive test in stand-down situation
§§40.149(b): Report to DER of changed test result
§40.155(a): Report to DER of dilute specimen
§40.167(b) and (c): Reports of test results to DER
§40.187(a) through (e): Reports to DER concerning the reconfirmation of tests
§40.191(d): Notice to DER concerning refusals to test
§40.193(b)(3): Notification to DER of refusal in shy bladder situation
§40.193(b)(4): Notification to DER of insufficient specimen
§40.193(b)(5): Transmission of CCF copies to DER (not to MRO)
§40.199: Report to DER of cancelled test and direction to DER for additional collection
§40.201: Report to DER of cancelled test

Alcohol Testing Information

§40.215: Notice to BATs and STTs of contact information for DER
§40.241(b)(1): Notification to DER that an employee is a "no show" for an alcohol test
§40.247(a)(2): Transmission of alcohol screening test results only when the test result is less than 0.02
§40.255(a)(4): Transmission of alcohol confirmation test results only when the test result is less than 0.02
§40.263(a)(3) and 263(b)(3): Notification of insufficient saliva and failure to provide sufficient amount of breath

[65 FR 79526, Dec. 19, 2000, as amended at 66 FR 41955, Aug. 9, 2001; 73 FR 35975, June 25, 2008]

Appendix G to Part 40—Alcohol Testing Form

The following form is the alcohol testing form required for use in the DOT alcohol testing program beginning August 1, 2010. Employers are authorized to use the form effective February 25, 2010.

[68 FR 43952, July 25, 2003, as amended 75 FR 8528, February 25, 2010]

U.S. Department of Transportation (DOT)
Alcohol Testing Form

(The instructions for completing this form are on the back of Copy 3)

Print Screening Results Here or Affix with Tamper Evident Tape

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, State, 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

STEP 2: TO BE COMPLETED BY EMPLOYEE

I certify that I am about to submit to alcohol testing required by US Department of Transportation regulations and that the identifying info is true and correct.

_____ ___/___/___
Signature of Employee Date Month Day Year

Print Confirmation Results Here or 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 tech own form.) I certify that I have conducted alcohol testing on the above named individual in accordance with the procedures estab of Transportation regulation, 49 CFR Part 40, that I am qualified to operate the testing device(s) identified, and that the re

TECHNICIAN: ☐ BAT ☐ STT **DEVICE:** ☐ SALIVA ☐ BREATH* 15-

SCREENING TEST: *(For BREATH DEVICE* write in the space below only if the testing device is not designed to print.)*

Test #	Testing Device Name	Device Serial # *OR* Lot # & Exp Date	Activation Time	Reading Time	Result

CONFIRMATION TEST: *Results MUST be affixed to each copy of this form or printed directly onto the form.*

REMARKS:

_____

_____

_____

Print Additional Results Here or Affix *With Tamper Evident Tape*

Alcohol Technician's Company **Company Street Address**

_____ _____ (___) _____
(PRINT) Alcohol Technician's Name (First, M.I., Last) Company City, State, Zip Phone Number

_____ ___/___/___
Signature of Alcohol Technician Date Month Day Year

STEP 4: TO BE COMPLETED BY EMPLOYEE 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 d duties, or operate heavy equipment because the results are 0.02 or greater.

_____ ___/___/___
Signature of Employee Date Month Day Year

Form DOT F 1380 (Rev. 5/2008) OMB No. 2105-0529

COPY 1 – ORIGINAL – FORWARD TO THE EMPLOYER

U.S. Department of Transportation (DOT)
Alcohol Testing Form

(The instructions for completing this form are on the back of Copy 3)

Print Screening Results Here or Affix with Tamper Evident Tape

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, State, 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

STEP 2: TO BE COMPLETED BY EMPLOYEE

I certify that I am about to submit to alcohol testing required by US Department of Transportation regulations and that the identifying info is true and correct.

Print Confirmation Results Here or Affix with Tamper Evident Tape

_____ ___/___/___
Signature of Employee Date Month Day Year

STEP 3: TO BE COMPLETED BY ALCOHOL TECHNICIAN

(If the technician conducting the screening test is not the same technician who will be conducting the confirmation test, each tech own form.) I certify that I have conducted alcohol testing on the above named individual in accordance with the procedures estab of Transportation regulation, 49 CFR Part 40, that I am qualified to operate the testing device(s) identified, and that the re

TECHNICIAN: ☐ BAT ☐ STT DEVICE: ☐ SALIVA ☐ BREATH* 15-

SCREENING TEST: *(For BREATH DEVICE* write in the space below only if the testing device is not designed to print.)*

Test #	Testing Device Name	Device Serial # *OR* Lot # & Exp Date	Activation Time	Reading Time	Result

CONFIRMATION TEST: *Results MUST be affixed to each copy of this form or printed directly onto the form.*

REMARKS:

Print Additional Results Here or Affix *With Tamper Evident Tape*

Alcohol Technician's Company Company Street Address

(PRINT) Alcohol Technician's Name (First, M.I., Last) Company City, State, Zip (___) Phone Number

_____ ___/___/___
Signature of Alcohol Technician Date Month Day Year

STEP 4: TO BE COMPLETED BY EMPLOYEE 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 d duties, or operate heavy equipment because the results are 0.02 or greater.

_____ ___/___/___
Signature of Employee Date Month Day Year

Form DOT F 1380 (Rev. 5/2008) OMB No. 2105-0529

COPY 2 – EMPLOYEE RETAINS

U.S. Department of Transportation (DOT) Alcohol Testing Form

(The instructions for completing this form are on the back of Copy 3)

Print Screening Results Here or Affix with Tamper Evident Tape

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, State, 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

STEP 2: TO BE COMPLETED BY EMPLOYEE

I certify that I am about to submit to alcohol testing required by US Department of Transportation regulations and that the identifying inf is true and correct.

_____ ___/___/___
Signature of Employee Date Month Day Year

Print Confirmation Results Here or 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 tec own form.) I certify that I have conducted alcohol testing on the above named individual in accordance with the procedures esta of Transportation regulation, 49 CFR Part 40, that I am qualified to operate the testing device(s) identified, and that the r

TECHNICIAN: ☐ BAT ☐ STT DEVICE: ☐ SALIVA ☐ BREATH* 15

SCREENING TEST: *(For BREATH DEVICE* write in the space below only if the testing device is not designed to print.)*

Test #	Testing Device Name	Device Serial # OR Lot # & Exp Date	Activation Time	Reading Time	Result

CONFIRMATION TEST: *Results MUST be affixed to each copy of this form or printed directly onto the form.*

REMARKS:

Print Additional Results Here or Affix *With Tamper Evident Tape*

Alcohol Technician's Company **Company Street Address**

(PRINT) Alcohol Technician's Name (First, M.I., Last) Company City, State, Zip (___) Phone Number

_____ ___/___/___
Signature of Alcohol Technician Date Month Day Year

STEP 4: TO BE COMPLETED BY EMPLOYEE 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 duties, or operate heavy equipment because the results are 0.02 or greater.

_____ ___/___/___
Signature of Employee Date Month Day Year

COPY 3 – ALCOHOL TECHNICIAN RETAINS

PAPERWORK REDUCTION ACT NOTICE (as required by 5 CFR 1320.21)

A federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a current valid OMB Control Number. The OMB Control Number for this information collection is 2105-0529. Public reporting for this collection of information is estimated to be approximately 8 minutes per response, including the time for reviewing instructions, completing and reviewing the collection of information. All responses to this collection of information are mandatory. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: Information Collection Clearance Officer, U.S. Department of Transportation, Office of Drug and Alcohol Policy and Compliance, 1200 New Jersey Avenue, SE, Suite W62-300, Washington, D.C. 20590.

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 be part of the printed record.

NOTE: Be sure to enter the result of the test exactly as it is indicated on the breath testing device, e.g., 0.00, 0.02, 0.04, etc. Affix the printed information to the front of the form in the space provided, or to the back of the form, in a tamper-evident manner (e.g., tape) such that it does not obscure the original printed information, 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.

Ensure that a waiting period of at least 15 minutes occurs before the confirmation test begins. Check the box indicating that the waiting period lasted at least 15 minutes.

After conducting the alcohol confirmation test, affix the printed information to the front of the form in the space provided, or to the back of the form, in a tamper-evident manner (e.g., tape) such that it does not obscure the original information, 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.

BACK OF PAGE 3

Appendix H to Part 40 – DOT Drug and Alcohol Testing Management Information System (MIS) Data Collection Form

The following form is the MIS Data Collection form required for use beginning in 2011 to report calendar year 2010 MIS data.

ATTACHMENT F-2

P R O T O C O L

Miami-Dade County Employee's Medical Assessment and Testing Procedures

PART 655–PREVENTION OF ALCOHOL MISUSE AND PROHIBITED DRUG USE IN TRANSIT OPERATIONS

[[Code of Federal Regulations]
[Title 49, Volume 7]
[Revised as of October 1, 2009]
From the U.S. Government Printing Office via GPO Access
[CITE: 49CFR655]

[Page 468-481]

TITLE 49--TRANSPORTATION

CHAPTER VI--FEDERAL TRANSIT ADMINISTRATION, DEPARTMENT OF TRANSPORTATION

PART 655_PREVENTION OF ALCOHOL MISUSE AND PROHIBITED DRUG USE IN TRANSIT OPERATIONS--Table of Contents

Subpart A_General

Sec.
655.1 Purpose.
655.2 Overview.
655.3 Applicability.
655.4 Definitions.
655.5 Stand-down waivers for drug testing.
655.6 Preemption of state and local laws.
655.7 Starting date for testing programs.

Subpart B_Program Requirements

655.11 Requirement to establish an anti-drug use and alcohol misuse program.
655.12 Required elements of an anti-drug use and alcohol misuse program.
655.13 [Reserved]
655.14 Education and training programs.
655.15 Policy statement contents.
655.16 Requirement to disseminate policy.
655.17 Notice requirement.
655.18-655.20 [Reserved]

Subpart C_Prohibited Drug Use

655.21 Drug testing.
655.22-655.30 [Reserved]

Subpart D_Prohibited Alcohol Use

655.31 Alcohol testing.
655.32 On duty use.
655.33 Pre-duty use.
655.34 Use following an accident.
655.35 Other alcohol-related conduct.
655.36-655.40 [Reserved]

Subpart E_Types of Testing

655.41 Pre-employment drug testing.
655.42 Pre-employment alcohol testing.
655.43 Reasonable suspicion testing.
655.44 Post-accident testing.
655.45 Random testing.
655.46 Return to duty following refusal to submit to a test, verified positive drug test result and/or breath alcohol test result of 0.04 or greater.
655.47 Follow-up testing after returning to duty.
655.48 Retesting of covered employees with an alcohol concentration of 0.02 or greater but less than 0.04.
655.49 Refusal to submit to a drug or alcohol test.
655.50 [Reserved]

Subpart F_Drug and Alcohol Testing Procedures

655.51 Compliance with testing procedures requirements.
655.52 Substance abuse professional (SAP).
655.53 Supervisor acting as collection site personnel.
655.54-655.60 [Reserved]

Subpart G_Consequences

655.61 Action when an employee has a verified positive drug test result or has a confirmed alcohol test result of 0.04 or greater, or refuses to submit to a test.
655.62 Referral, evaluation, and treatment.
655.63-655.70 [Reserved]

Subpart H_Administrative Requirements

655.71 Retention of records.
655.72 Reporting of results in a management information system.
655.73 Access to facilities and records.
655.74-655.80 [Reserved]

Subpart I_Certifying Compliance

655.81 Grantee oversight responsibility.
655.82 Compliance as a condition of financial assistance.

655.83 Requirement to certify compliance.

Authority: 49 U.S.C. 5331; 49 CFR 1.51.

Source: 66 FR 42002, Aug. 9, 2001, unless otherwise noted.

Subpart A_General

Sec. 655.1 Purpose.

The purpose of this part is to establish programs to be implemented by employers that receive financial assistance from the Federal Transit Administration (FTA) and by contractors of

[[Page 469]]

those employers, that are designed to help prevent accidents, injuries, and fatalities resulting from the misuse of alcohol and use of prohibited drugs by employees who perform safety-sensitive functions.

Sec. 655.2 Overview.

(a) This part includes nine subparts. Subpart A of this part covers the general requirements of FTA's drug and alcohol testing programs. Subpart B of this part specifies the basic requirements of each employer's alcohol misuse and prohibited drug use program, including the elements required to be in each employer's testing program. Subpart C of this part describes prohibited drug use. Subpart D of this part describes prohibited alcohol use. Subpart E of this part describes the types of alcohol and drug tests to be conducted. Subpart F of this part addresses the testing procedural requirements mandated by the Omnibus Transportation Employee Testing Act of 1991, and as required in 49 CFR Part 40. Subpart G of this part lists the consequences for covered employees who engage in alcohol misuse or prohibited drug use. Subpart H of this part contains administrative matters, such as reports and recordkeeping requirements. Subpart I of this part specifies how a recipient certifies compliance with the rule.

(b) This part must be read in conjunction with 49 CFR Part 40, Procedures for Transportation Workplace Drug and Alcohol Testing Programs.

Sec. 655.3 Applicability.

(a) Except as specifically excluded in paragraphs (b), and (c) of this section, this part applies to:

(1) Each recipient and subrecipient receiving Federal assistance under:

(i) 49 U.S.C. 5307, 5309, or 5311; or

(ii) 23 U.S.C. 103(e)(4); and

(2) Any contractor of a recipient or subrecipient of Federal assistance under:

(i) 49 U.S.C. 5307, 5309, or 5311; or

(ii) 23 U.S.C. 103(e)(4).

(b) A recipient operating a railroad regulated by the Federal Railroad Administration (FRA) shall follow 49 CFR Part 219 and Sec. 655.83 for its railroad operations, and shall follow this part for its non-railroad operations, if any.

(c) A recipient operating a ferryboat regulated by the United States Coast Guard (USCG) that satisfactorily complies with the testing requirements of 46 CFR Parts 4 and 16, and 33 CFR Part 95 shall be in concurrent compliance with the testing requirements of this part. This exception shall not apply to the provisions of section 655.45, or subparts G, or H of this part.

[66 FR 42002, Aug. 9, 2001, as amended at 71 FR 69198, Nov. 30, 2006]

Sec. 655.4 Definitions.

For this part, the terms listed in this section have the following definitions. The definitions of additional terms used in this part but not listed in this section can be found in 49 CFR Part 40.

Accident means an occurrence associated with the operation of a vehicle, if as a result:

(1) An individual dies; or

(2) An individual suffers bodily injury and immediately receives medical treatment away from the scene of the accident; or

(3) With respect to an occurrence in which the mass transit vehicle involved is a bus, electric bus, van, or automobile, one or more vehicles (including non-FTA funded vehicles) incurs disabling damage as the result of the occurrence and such vehicle or vehicles are transported away from the scene by a tow truck or other vehicle; or

(4) With respect to an occurrence in which the mass transit vehicle involved is a rail car, trolley car, trolley bus, or vessel, the mass transit vehicle is removed from operation.

Administrator means the Administrator of the Federal Transit Administration or the Administrator's designee.

Anti-drug program means a program to detect and deter the use of prohibited drugs as required by this part.

Certification means a recipient's written statement, authorized by the organization's governing board or other authorizing official that the recipient has complied with the provisions of this part. (See Sec. 655.82 and Sec. 655.83 for certification requirements.)

Contractor means a person or organization that provides a safety-sensitive service for a recipient, subrecipient, employer, or operator consistent with a specific understanding or arrangement. The understanding can be a written contract or an informal arrangement that reflects an ongoing relationship between the parties.

Covered employee means a person, including an applicant or transferee, who performs or will perform a safety-sensitive function for an entity subject to this part. A volunteer is a covered employee if:

(1) The volunteer is required to hold a commercial driver's license to operate the vehicle; or

(2) The volunteer performs a safety-sensitive function for an entity subject to this part and receives remuneration in excess of his or her actual expenses incurred while engaged in the volunteer activity.

Disabling damage means damage that precludes departure of a motor vehicle from the scene of the accident in its usual manner in daylight after simple repairs.

(1) Inclusion. Damage to a motor vehicle, where the vehicle could have been driven, but would have been further damaged if so driven.

(2) Exclusions. (i) Damage that can be remedied temporarily at the scene of the accident without special tools or parts.

(ii) Tire disablement without other damage even if no spare tire is available.

(iii) Headlamp or tail light damage.

(iv) Damage to turn signals, horn, or windshield wipers, which makes the vehicle inoperable.

DOT or The Department means the United States Department of Transportation.

DOT agency means an agency (or ``operating administration'') of the United States Department of Transportation administering regulations requiring drug and alcohol testing. See 14 CFR part 121, appendices I and J; 33 CFR part 95; 46 CFR parts 4, 5, and 16; and 49 CFR parts 199, 219, 382, and 655.

Employer means a recipient or other entity that provides mass transportation service or which performs a safety-sensitive function for such recipient or other entity. This term includes subrecipients, operators, and contractors.

FTA means the Federal Transit Administration, an agency of the U.S. Department of Transportation.

Performing (a safety-sensitive function) means a covered employee is considered to be performing a safety-sensitive function and includes any period in which he or she is actually performing, ready to perform, or immediately available to perform such functions.

Positive rate for random drug testing means the number of verified positive results for random drug tests conducted under this part plus the number of refusals of random drug tests required by this part, divided by the total number of random drug tests results (i.e., positive, negative, and refusals) under this part.

Railroad means:

(1) All forms of non-highway ground transportation that run on rails or electromagnetic guideways, including:

(i) Commuter or other short-haul rail passenger service in a metropolitan or suburban area, as well as any commuter rail service that was operated by the Consolidated Rail Corporation as of January 1, 1979; and

(ii) High speed ground transportation systems that connect metropolitan areas, without regard to whether they use new technologies not associated with traditional railroads.

(2) Such term does not include rapid transit operations within an urban area that are not connected to the general railroad system of transportation.

Recipient means an entity receiving Federal financial assistance under 49 U.S.C. 5307, 5309, or 5311; or under 23 U.S.C. 103(e)(4).

Refuse to submit means any circumstance outlined in 49 CFR 40.191 and 40.261.

Safety-sensitive function means any of the following duties, when performed by employees of recipients, subrecipients, operators, or contractors:

(1) Operating a revenue service vehicle, including when not in revenue service;

(2) Operating a nonrevenue service vehicle, when required to be operated

[[Page 471]]

by a holder of a Commercial Driver's License;

(3) Controlling dispatch or movement of a revenue service vehicle;

(4) Maintaining (including repairs, overhaul and rebuilding) a revenue service vehicle or equipment used in revenue service. This section does not apply to the following: an employer who receives funding under 49 U.S.C. 5307 or 5309, is in an area less than 200,000 in population, and contracts out such services; or an employer who receives funding under 49 U.S.C. 5311 and contracts out such services;

(5) Carrying a firearm for security purposes.

Vehicle means a bus, electric bus, van, automobile, rail car, trolley car, trolley bus, or vessel. A mass transit vehicle is a vehicle used for mass transportation or for ancillary services.

Violation rate for random alcohol testing means the number of 0.04 and above random alcohol confirmation test results conducted under this part plus the number of refusals of random alcohol tests required by this part, divided by the total number of alcohol random screening tests (including refusals) conducted under this part.

[66 FR 42002, Aug. 9, 2001, as amended at 68 FR 75462, Dec. 31, 2003]

Sec. 655.5 Stand-down waivers for drug testing.

(a) An employer subject to this part may petition the FTA for a waiver allowing the employer to stand down, per 49 CFR Part 40, an employee following a report of a laboratory confirmed positive drug test or refusal, pending the outcome of the verification process.

(b) Each petition for a waiver must be in writing and include facts and justification to support the waiver. Each petition must satisfy the requirements for obtaining a waiver, as provided in 49 CFR 40.21.

(c) Each petition for a waiver must be submitted to the Office of Safety and Security, Federal Transit Administration, U.S. Department of Transportation, 400 Seventh Street, SW. Washington, DC 20590.

(d) The Administrator may grant a waiver subject to 49 CFR 40.21(d).

Sec. 655.6 Preemption of state and local laws.

(a) Except as provided in paragraph (b) of this section, this part preempts any state or local law, rule, regulation, or order to the extent that:

(1) Compliance with both the state or local requirement and any requirement in this part is not possible; or

(2) Compliance with the state or local requirement is an obstacle to the accomplishment and execution of any requirement in this part.

(b) This part shall not be construed to preempt provisions of state criminal laws that impose sanctions for reckless conduct attributed to prohibited drug use or alcohol misuse leading to actual loss of life, injury, or damage to property, whether the provisions apply specifically to transportation employees or employers or to the general public.

Sec. 655.7 Starting date for testing programs.

An employer must have an anti-drug and alcohol misuse testing program in place by the date the employer begins operations.

Subpart B_Program Requirements

Sec. 655.11 Requirement to establish an anti-drug use and alcohol misuse program.

Each employer shall establish an anti-drug use and alcohol misuse program consistent with the requirements of this part.

Sec. 655.12 Required elements of an anti-drug use and alcohol misuse program.

An anti-drug use and alcohol misuse program shall include the following:

(a) A statement describing the employer's policy on prohibited drug use and alcohol misuse in the workplace, including the consequences associated with prohibited drug use and alcohol misuse. This policy statement shall include all of the elements specified in Sec. 655.15. Each employer shall disseminate the policy consistent with the provisions of Sec. 655.16.

(b) An education and training program which meets the requirements of Sec. 655.14.

[[Page 472]]

(c) A testing program, as described in Subparts C and D of this part, which meets the requirements of this part and 49 CFR Part 40.

(d) Procedures for referring a covered employee who has a verified positive drug test result or an alcohol concentration of 0.04 or greater to a Substance Abuse Professional, consistent with 49 CFR Part 40.

Sec. 655.13 [Reserved]

Sec. 655.14 Education and training programs.

Each employer shall establish an employee education and training program for all covered employees, including:

(a) Education. The education component shall include display and distribution to every covered employee of: informational material and a community service hot-line telephone number for employee assistance, if available.

(b) Training--(1) Covered employees. Covered employees must receive at least 60 minutes of training on the effects and consequences of prohibited drug use on personal health, safety, and the work environment, and on the signs and symptoms that may indicate prohibited drug use.

(2) Supervisors. Supervisors and/or other company officers authorized by the employer to make reasonable suspicion determinations shall receive at least 60 minutes of training on the physical, behavioral, and performance indicators of probable drug use and at least 60 minutes of training on the physical, behavioral, speech, and performance indicators of probable alcohol misuse.

Sec. 655.15 Policy statement contents.

The local governing board of the employer or operator shall adopt an anti-drug and alcohol misuse policy statement. The statement must be made available to each covered employee, and shall include the

following:

(a) The identity of the person, office, branch and/or position designated by the employer to answer employee questions about the employer's anti-drug use and alcohol misuse programs.

(b) The categories of employees who are subject to the provisions of this part.

(c) Specific information concerning the behavior and conduct prohibited by this part.

(d) The specific circumstances under which a covered employee will be tested for prohibited drugs or alcohol misuse under this part.

(e) The procedures that will be used to test for the presence of illegal drugs or alcohol misuse, protect the employee and the integrity of the drug and alcohol testing process, safeguard the validity of the test results, and ensure the test results are attributed to the correct covered employee.

(f) The requirement that a covered employee submit to drug and alcohol testing administered in accordance with this part.

(g) A description of the kind of behavior that constitutes a refusal to take a drug or alcohol test, and a statement that such a refusal constitutes a violation of the employer's policy.

(h) The consequences for a covered employee who has a verified positive drug or a confirmed alcohol test result with an alcohol concentration of 0.04 or greater, or who refuses to submit to a test under this part, including the mandatory requirements that the covered employee be removed immediately from his or her safety-sensitive function and be evaluated by a substance abuse professional, as required by 49 CFR Part 40.

(i) The consequences, as set forth in Sec. 655.35 of subpart D, for a covered employee who is found to have an alcohol concentration of 0.02 or greater but less than 0.04.

(j) The employer shall inform each covered employee if it implements elements of an anti-drug use or alcohol misuse program that are not required by this part. An employer may not impose requirements that are inconsistent with, contrary to, or frustrate the provisions of this part.

Sec. 655.16 Requirement to disseminate policy.

Each employer shall provide written notice to every covered employee and to representatives of employee organizations of the employer's anti-drug and alcohol misuse policies and procedures.

[[Page 473]]

Sec. 655.17 Notice requirement.

Before performing a drug or alcohol test under this part, each

employer shall notify a covered employee that the test is required by this part. No employer shall falsely represent that a test is administered under this part.

Sec. Sec. 655.18-655.20 [Reserved]

Subpart C_Prohibited Drug Use

Sec. 655.21 Drug testing.

(a) An employer shall establish a program that provides testing for prohibited drugs and drug metabolites in the following circumstances: pre-employment, post-accident, reasonable suspicion, random, and return to duty/follow-up.

(b) When administering a drug test, an employer shall ensure that the following drugs are tested for:

(1) Marijuana;

(2) Cocaine;

(3) Opiates;

(4) Amphetamines; and

(5) Phencyclidine.

(c) Consumption of these products is prohibited at all times.

Sec. Sec. 655.22-655.30 [Reserved]

Subpart D_Prohibited Alcohol Use

Sec. 655.31 Alcohol testing.

(a) An employer shall establish a program that provides for testing for alcohol in the following circumstances: post-accident, reasonable suspicion, random, and return to duty/follow-up. An employer may also conduct pre-employment alcohol testing.

(b) Each employer shall prohibit a covered employee, while having an alcohol concentration of 0.04 or greater, from performing or continuing to perform a safety-sensitive function.

Sec. 655.32 On duty use.

Each employer shall prohibit a covered employee from using alcohol while performing safety-sensitive functions. No employer having actual knowledge that a covered employee is using alcohol while performing

safety-sensitive functions shall permit the employee to perform or continue to perform safety-sensitive functions.

Sec. 655.33 Pre-duty use.

(a) General. Each employer shall prohibit a covered employee from using alcohol within 4 hours prior to performing safety-sensitive functions. No employer having actual knowledge that a covered employee has used alcohol within four hours of performing a safety-sensitive function shall permit the employee to perform or continue to perform safety-sensitive functions.

(b) On-call employees. An employer shall prohibit the consumption of alcohol for the specified on-call hours of each covered employee who is on-call. The procedure shall include:

(1) The opportunity for the covered employee to acknowledge the use of alcohol at the time he or she is called to report to duty and the inability to perform his or her safety-sensitive function.

(2) The requirement that the covered employee take an alcohol test, if the covered employee has acknowledged the use of alcohol, but claims ability to perform his or her safety-sensitive function.

Sec. 655.34 Use following an accident.

Each employer shall prohibit alcohol use by any covered employee required to take a post-accident alcohol test under Sec. 655.44 for eight hours following the accident or until he or she undergoes a post-accident alcohol test, whichever occurs first.

Sec. 655.35 Other alcohol-related conduct.

(a) No employer shall permit a covered employee tested under the provisions of subpart E of this part who is found to have an alcohol concentration of 0.02 or greater but less than 0.04 to perform or continue to perform safety-sensitive functions, until:

(1) The employee's alcohol concentration measures less than 0.02; or

(2) The start of the employee's next regularly scheduled duty period, but not less than eight hours following administration of the test.

(b) Except as provided in paragraph (a) of this section, no employer shall take any action under this part against an employee based solely on test results showing an alcohol concentration less than 0.04. This does not prohibit an employer with authority independent

[[Page 474]]

of this part from taking any action otherwise consistent with law.

Sec. Sec. 655.36-655.40 [Reserved]

Subpart E_Types of Testing

Sec. 655.41 Pre-employment drug testing.

(a)(1) Before allowing a covered employee or applicant to perform a safety-sensitive function for the first time, the employer must ensure that the employee takes a pre-employment drug test administered under this part with a verified negative result. An employer may not allow a covered employee, including an applicant, to perform a safety-sensitive function unless the employee takes a drug test administered under this part with a verified negative result.

(2) When a covered employee or applicant has previously failed or refused a pre-employment drug test administered under this part, the employee must provide the employer proof of having successfully completed a referral, evaluation and treatment plan as described in Sec. 655.62.

(b) An employer may not transfer an employee from a nonsafety-sensitive function to a safety-sensitive function until the employee takes a pre-employment drug test administered under this part with a verified negative result.

(c) If a pre-employment drug test is canceled, the employer shall require the covered employee or applicant to take another pre-employment drug test administered under this part with a verified negative result.

(d) When a covered employee or applicant has not performed a safety-sensitive function for 90 consecutive calendar days regardless of the reason, and the employee has not been in the employer's random selection pool during that time, the employer shall ensure that the employee takes a pre-employment drug test with a verified negative result.

Sec. 655.42 Pre-employment alcohol testing.

An employer may, but is not required to, conduct pre-employment alcohol testing under this part. If an employer chooses to conduct pre-employment alcohol testing, the employer must comply with the following requirements:

(a) The employer 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).

(b) The employer must treat all covered employees performing safety-sensitive functions the same for the purpose of pre-employment alcohol testing (i.e., you must not test some covered employees and not others).

(c) The employer 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.

(d) The employer must conduct all pre-employment alcohol tests using the alcohol testing procedures set forth in 49 CFR Part 40.

(e) The employer 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 0.02.

Sec. 655.43 Reasonable suspicion testing.

(a) An employer shall conduct a drug and/or alcohol test when the employer has reasonable suspicion to believe that the covered employee has used a prohibited drug and/or engaged in alcohol misuse.

(b) An employer's determination that reasonable suspicion exists shall be based on specific, contemporaneous, articulable observations concerning the appearance, behavior, speech, or body odors of the covered employee. A supervisor(s), or other company official(s) who is trained in detecting the signs and symptoms of drug use and alcohol misuse must make the required observations.

(c) Alcohol testing is authorized under this section only if the observations required by paragraph (b) of this section are made during, just preceding, or just after the period of the workday that the covered employee is required to be in compliance with this part. An employer may direct a covered employee to undergo reasonable

[[Page 475]]

suspicion testing for alcohol only while the employee is performing safety-sensitive functions; just before the employee is to perform safety-sensitive functions; or just after the employee has ceased performing such functions.

(d) If an alcohol test required by this section is not administered within two hours following the determination under paragraph (b) of this section, 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 (b) of this section, the employer shall cease attempts to administer an alcohol test and shall state in the record the reasons for not administering the test.

Sec. 655.44 Post-accident testing.

(a) Accidents. (1) Fatal accidents. (i) As soon as practicable following an accident involving the loss of human life, an employer shall conduct drug and alcohol tests on each surviving covered employee

operating the mass transit vehicle at the time of the accident. Post-accident drug and alcohol testing of the operator is not required under this section if the covered employee is tested under the fatal accident testing requirements of the Federal Motor Carrier Safety Administration rule 49 CFR 389.303(a)(1) or (b)(1).

(ii) The employer shall also drug and alcohol test any other covered employee whose performance could have contributed to the accident, as determined by the employer using the best information available at the time of the decision.

(2) Nonfatal accidents. (i) As soon as practicable following an accident not involving the loss of human life in which a mass transit vehicle is involved, the employer shall drug and alcohol test each covered employee operating the mass transit vehicle at the time of the accident unless the employer determines, using the best information available at the time of the decision, that the covered employee's performance can be completely discounted as a contributing factor to the accident. The employer shall also drug and alcohol test any other covered employee whose performance could have contributed to the accident, as determined by the employer using the best information available at the time of the decision.

(ii) If an alcohol 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 alcohol test was not promptly administered. If an alcohol 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 maintain the record. Records shall be submitted to FTA upon request of the Administrator.

(b) An employer shall ensure that a covered employee required to be drug tested under this section is tested as soon as practicable but within 32 hours of the accident.

(c) A covered employee who is subject to post-accident testing who fails to remain readily available for such testing, including notifying the employer or the employer representative of his or her location if he or she leaves the scene of the accident prior to submission to such test, may be deemed by the employer to have refused to submit to testing.

(d) The decision not to administer a drug and/or alcohol test under this section shall be based on the employer's determination, using the best available information at the time of the determination that the employee's performance could not have contributed to the accident. Such a decision must be documented in detail, including the decision-making process used to reach the decision not to test.

(e) Nothing in this section shall be construed to require the delay of necessary medical attention for the injured following an accident or to prohibit a covered employee 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.

(f) The results of a blood, urine, or breath test for the use of

prohibited drugs or alcohol misuse, conducted by Federal, State, or local officials having independent authority for the test,

[[Page 476]]

shall be considered to meet the requirements of this section provided such test conforms to the applicable Federal, State, or local testing requirements, and that the test results are obtained by the employer. Such test results may be used only when the employer is unable to perform a post-accident test within the required period noted in paragraphs (a) and (b) of this section.

Sec. 655.45 Random testing.

(a) Except as provided in paragraphs (b) through (d) of this section, the minimum annual percentage rate for random drug testing shall be 50 percent of covered employees; the random alcohol testing rate shall be 10 percent. As provided in paragraph (b) of this section, this rate is subject to annual review by the Administrator.

(b) The Administrator's decision to increase or decrease the minimum annual percentage rate for random drug and alcohol testing is based, respectively, on the reported positive drug and alcohol violation rates for the entire industry. All information used for this determination is drawn from the drug and alcohol Management Information System (MIS) reports required by this part. In order to ensure reliability of the data, the Administrator shall consider 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's verified positive results and violation rates. Each year, the Administrator will publish in the Federal Register the minimum annual percentage rates for random drug and alcohol testing of covered employees. The new minimum annual percentage rate for random drug and alcohol testing will be applicable starting January 1 of the calendar year following publication.

(c) Rates for drug testing. (1) When the minimum annual percentage rate for random drug testing is 50 percent, the Administrator may lower this rate to 25 percent of all covered employees if the Administrator determines that the data received under the reporting requirements of Sec. 655.72 for the two preceding consecutive calendar years indicate that the reported positive rate is less than 1.0 percent.

(2) When the minimum annual percentage rate for random drug testing is 25 percent, and the data received under the reporting requirements of Sec. 655.72 for the calendar year indicate that the reported positive rate is equal to or greater than 1.0 percent, the Administrator will increase the minimum annual percentage rate for random drug or random alcohol testing to 50 percent of all covered employees.

(d) Rates for alcohol testing. (1)(i) When the minimum annual percentage rate for random alcohol testing is 25 percent or more, the

Administrator may lower this rate to 10 percent of all covered employees if the Administrator determines that the data received under the reporting requirements of Sec. 655.72 for two consecutive calendar years indicate that the violation rate is less than 0.5 percent.

(ii) When the minimum annual percentage rate for random alcohol testing is 50 percent, the Administrator may lower this rate to 25 percent of all covered employees if the Administrator determines that the data received under the reporting requirements of Sec. 655.72 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.

(2)(i) When the minimum annual percentage rate for random alcohol testing is 10 percent, and the data received under the reporting requirements of Sec. 655.72 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 Administrator will increase the minimum annual percentage rate for random alcohol testing to 25 percent of all covered employees.

(ii) When the minimum annual percentage rate for random alcohol testing is 25 percent or less, and the data received under the reporting requirements of Sec. 655.72 for that calendar year indicate that the violation rate is equal to or greater than 1.0 percent, the Administrator will increase the minimum annual percentage rate for random alcohol testing to 50 percent of all covered employees.

(e) The selection of employees for random drug and alcohol testing shall

[[Page 477]]

be made by a scientifically valid method, such as a random number table or a computer-based random number generator that is matched with employees' Social Security numbers, payroll identification numbers, or other comparable identifying numbers. Under the selection process used, each covered employee shall have an equal chance of being tested each time selections are made.

(f) The employer shall randomly select a sufficient number of covered employees for testing during each calendar year to equal an annual rate not less than the minimum annual percentage rates for random drug and alcohol testing determined by the Administrator. If the employer conducts random drug and alcohol testing through a consortium, the number of employees to be tested may be calculated for each individual employer or may be based on the total number of covered employees covered by the consortium who are subject to random drug and alcohol testing at the same minimum annual percentage rate under this part.

(g) Each employer shall ensure that random drug and alcohol tests conducted under this part are unannounced and unpredictable, and that the dates for administering random tests are spread reasonably throughout the calendar year. Random testing must be conducted at all times of day when safety-sensitive functions are performed.

(h) Each employer shall require that each covered employee who is notified of selection for random drug or random alcohol testing proceed to the test site immediately. If the employee is performing a safety-sensitive function at the time of the notification, the employer shall instead ensure that the employee ceases to perform the safety-sensitive function and proceeds to the testing site immediately.

(i) A covered employee shall only be randomly tested for alcohol misuse while the employee is performing safety-sensitive functions; just before the employee is to perform safety-sensitive functions; or just after the employee has ceased performing such functions. A covered employee may be randomly tested for prohibited drug use anytime while on duty.

(j) If a given covered employee is subject to random drug and alcohol testing under the testing rules of more than one DOT agency for the same employer, the employee shall be subject to random drug and alcohol testing at the percentage rate established for the calendar year by the DOT agency regulating more than 50 percent of the employee's function.

(k) If an employer is required to conduct random drug and alcohol testing under the drug and alcohol testing rules of more than one DOT agency, the employer may--

(1) Establish separate pools for random selection, with each pool containing the covered employees who are subject to testing at the same required rate; or

(2) Randomly select such employees for testing at the highest percentage rate established for the calendar year by any DOT agency to which the employer is subject.

Sec. 655.46 Return to duty following refusal to submit to a test, verified positive drug test result and/or breath alcohol test result

of 0.04 or greater.

Where a covered employee refuses to submit to a test, has a verified positive drug test result, and/or has a confirmed alcohol test result of 0.04 or greater, the employer, before returning the employee to duty to perform a safety-sensitive function, shall follow the procedures outlined in 49 CFR Part 40.

Sec. 655.47 Follow-up testing after returning to duty.

An employer shall conduct follow-up testing of each employee who returns to duty, as specified in 49 CFR Part 40, subpart O.

Sec. 655.48 Retesting of covered employees with an alcohol concentration of 0.02 or greater but less than 0.04.

If an employer chooses to permit a covered employee to perform a safety-sensitive function within 8 hours of an alcohol test indicating an alcohol concentration of 0.02 or greater but less than 0.04, the employer shall retest the covered employee to ensure compliance with the provisions of Sec. 655.35. The covered employee may not perform safety-

[[Page 478]]

sensitive functions unless the confirmation alcohol test result is less than 0.02.

Sec. 655.49 Refusal to submit to a drug or alcohol test.

(a) Each employer shall require a covered employee to submit to a post-accident drug and alcohol test required under Sec. 655.44, a random drug and alcohol test required under Sec. 655.45, a reasonable suspicion drug and alcohol test required under Sec. 655.43, or a follow-up drug and alcohol test required under Sec. 655.47. No employer shall permit an employee who refuses to submit to such a test to perform or continue to perform safety-sensitive functions.

(b) When an employee refuses to submit to a drug or alcohol test, the employer shall follow the procedures outlined in 49 CFR Part 40.

Sec. 655.50 [Reserved]

Subpart F_Drug and Alcohol Testing Procedures

Sec. 655.51 Compliance with testing procedures requirements.

The drug and alcohol testing procedures in 49 CFR Part 40 apply to employers covered by this part, and must be read together with this part, unless expressly provided otherwise in this part.

Sec. 655.52 Substance abuse professional (SAP).

The SAP must perform the functions in 49 CFR Part 40.

Sec. 655.53 Supervisor acting as collection site personnel.

An employer shall not permit an employee with direct or immediate supervisory responsibility or authority over another employee to serve as the urine collection person, breath alcohol technician, or saliva-

testing technician for a drug or alcohol test of the employee.

Sec. Sec. 655.54-655.60 [Reserved]

Subpart G_Consequences

Sec. 655.61 Action when an employee has a verified positive drug test result or has a confirmed alcohol test result of 0.04 or greater, or

refuses to submit to a test.

(a) (1) Immediately after receiving notice from a medical review officer (MRO) or a consortium/third party administrator (C/TPA) that a covered employee has a verified positive drug test result, the employer shall require that the covered employee cease performing a safety-sensitive function.

(2) Immediately after receiving notice from a Breath Alcohol Technician (BAT) that a covered employee has a confirmed alcohol test result of 0.04 or greater, the employer shall require that the covered employee cease performing a safety-sensitive function.

(3) If an employee refuses to submit to a drug or alcohol test required by this part, the employer shall require that the covered employee cease performing a safety-sensitive function.

(b) Before allowing the covered employee to resume performing a safety-sensitive function, the employer shall ensure the employee meets the requirements of 49 CFR Part 40 for returning to duty, including taking a return to duty drug and/or alcohol test.

Sec. 655.62 Referral, evaluation, and treatment.

If a covered employee has a verified positive drug test result, or has a confirmed alcohol test of 0.04 or greater, or refuses to submit to a drug or alcohol test required by this part, the employer shall advise the employee of the resources available for evaluating and resolving problems associated with prohibited drug use and alcohol misuse, including the names, addresses, and telephone numbers of substance abuse professionals (SAPs) and counseling and treatment programs.

[[Page 479]]

Sec. Sec. 655.63-655.70 [Reserved]

Subpart H_Administrative Requirements

Sec. 655.71 Retention of records.

(a) General requirement. An employer shall maintain records of its anti-drug and alcohol misuse program as provided in this section. The records shall be maintained in a secure location with controlled access.

(b) Period of retention. In determining compliance with the retention period requirement, each record shall be maintained for the specified minimum period of time as measured from the date of the creation of the record. Each employer shall maintain the records in accordance with the following schedule:

(1) Five years. Records of covered employee verified positive drug or alcohol test results, documentation of refusals to take required drug or alcohol tests, and covered employee referrals to the substance abuse professional, and copies of annual MIS reports submitted to FTA.

(2) Two years. Records related to the collection process and employee training.

(3) One year. Records of negative drug or alcohol test results.

(c) Types of records. The following specific records must be maintained:

(1) Records related to the collection process:

(i) Collection logbooks, if used.

(ii) Documents relating to the random selection process.

(iii) Documents generated in connection with decisions to administer reasonable suspicion drug or alcohol tests.

(iv) Documents generated in connection with decisions on post-accident drug and alcohol testing.

(v) MRO documents verifying existence of a medical explanation of the inability of a covered employee to provide an adequate urine or breathe sample.

(2) Records related to test results:

(i) The employer's copy of the custody and control form.

(ii) Documents related to the refusal of any covered employee to submit to a test required by this part.

(iii) Documents presented by a covered employee to dispute the result of a test administered under this part.

(3) Records related to referral and return to duty and follow-up testing: Records concerning a covered employee's entry into and completion of the treatment program recommended by the substance abuse professional.

(4) Records related to employee training:

(i) Training materials on drug use awareness and alcohol misuse, including a copy of the employer's policy on prohibited drug use and alcohol misuse.

(ii) Names of covered employees attending training on prohibited drug use and alcohol misuse and the dates and times of such training.

(iii) Documentation of training provided to supervisors for the purpose of qualifying the supervisors to make a determination concerning

the need for drug and alcohol testing based on reasonable suspicion.

(iv) Certification that any training conducted under this part complies with the requirements for such training.

(5) Copies of annual MIS reports submitted to FTA.

Sec. 655.72 Reporting of results in a management information system.

(a) Each recipient shall annually prepare and maintain a summary of the results of its anti-drug and alcohol misuse testing programs performed under this part during the previous calendar year.

(b) When requested by FTA, each recipient shall submit to FTA's Office of Safety and Security, or its designated agent, by March 15, a report covering the previous calendar year (January 1 through December 31) summarizing the results of its anti-drug and alcohol misuse programs.

(c) Each recipient shall be responsible for ensuring the accuracy and timeliness of each report submitted by an employer, contractor, consortium or joint enterprise or by a third party service provider acting on the recipient's or employer's behalf.

(d) As an employer, you must use the Management Information System

[[Page 480]]

(MIS) form and instructions as required by 49 CFR part 40, Sec. 40.25 and appendix H. You may also use the electronic version of the MIS form provided by the DOT. The Administrator may designate means (e.g., electronic program transmitted via the Internet), other than hard-copy, for MIS form submission. For information on where to submit MIS forms and for the electronic version of the form, see: http://transit-safety.volpe.dot.gov/DAMIS.

(e) To calculate the total number of covered employees eligible for random testing throughout the year, as an employer, you must add the total number of covered employees eligible for testing during each random testing period for the year and divide that total by the number of random testing periods. Covered employees, and only covered employees, are to be in an employer's random testing pool, and all covered employees must be in the random pool. If you are an employer conducting random testing 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. As an employer, you may use a service agent (e.g., C/TPA) to perform random selections for you; and your covered employees may be part of a larger random testing pool of covered employees. However, you must ensure that the service agent you use is testing at the appropriate percentage established for your industry and that only covered employees are in the random testing pool.

(f) If you have a covered employee who performs multi-DOT agency functions (e.g., an employee drives a paratransit vehicle and performs

pipeline maintenance duties for you), count the employee only on the MIS report for the DOT agency under which he or she is random tested. Normally, this will be the DOT agency under which the employee performs more than 50% of his or her duties. Employers may have to explain the testing data for these employees in the event of a DOT agency inspection or audit.

(g) A service agent (e.g., Consortia/Third Party Administrator as defined in 49 CFR part 40) may prepare the MIS report on behalf of an employer. However, a company official (e.g., Designated Employer Representative as defined in 49 CFR part 40) must certify the accuracy and completeness of the MIS report, no matter who prepares it.

[66 FR 42002, Aug. 9, 2001, as amended at 68 FR 75462, Dec. 31, 2003]

Sec. 655.73 Access to facilities and records.

(a) Except as required by law, or expressly authorized or required in this section, no employer may release information pertaining to a covered employee that is contained in records required to be maintained by Sec. 655.71.

(b) A covered employee is entitled, upon written request, to obtain copies of any records pertaining to the covered employee's use of prohibited drugs or misuse of alcohol, including any records pertaining to his or her drug or alcohol tests. The employer shall provide promptly the records requested by the employee. Access to a covered employee's records shall not be contingent upon the employer's receipt of payment for the production of those records.

(c) An employer shall permit access to all facilities utilized and records compiled in complying with the requirements of this part to the Secretary of Transportation or any DOT agency with regulatory authority over the employer or any of its employees or to a State oversight agency authorized to oversee rail fixed guideway systems.

(d) An employer shall disclose data for its drug and alcohol testing programs, and any other information pertaining to the employer's anti-drug and alcohol misuse programs required to be maintained by this part, to the Secretary of Transportation or any DOT agency with regulatory authority over the employer or covered employee or to a State oversight agency authorized to oversee rail fixed guideway systems, upon the Secretary's request or the respective agency's request.

(e) When requested by the National Transportation Safety Board as part of an accident investigation, employers shall disclose information related to the employer's drug or alcohol testing related to the accident under investigation.

[[Page 481]]

(f) Records shall be made available to a subsequent employer upon receipt of a written request from the covered employee. Subsequent

disclosure by the employer is permitted only as expressly authorized by the terms of the covered employee's request.

(g) An employer may disclose information required to be maintained under this part pertaining to a covered employee to the employee or the decisionmaker in a lawsuit, grievance, or other proceeding initiated by or on behalf of the individual, and arising from the results of a drug or alcohol test under this part (including, but not limited to, a worker's compensation, unemployment compensation, or other proceeding relating to a benefit sought by the covered employee.)

(h) An employer shall release information regarding a covered employee's record as directed by the specific, written consent of the employee authorizing release of the information to an identified person.

(i) An employer may disclose drug and alcohol testing information required to be maintained under this part, pertaining to a covered employee, to the State oversight agency or grantee required to certify to FTA compliance with the drug and alcohol testing procedures of 49 CFR parts 40 and 655.

Sec. Sec. 655.74-655.80 [Reserved]

Subpart I_Certifying Compliance

Sec. 655.81 Grantee oversight responsibility.

A grantee shall ensure that the recipients of funds under 49 U.S.C. 5307, 5309, 5311 or 23 U.S.C. 103(e)(4) comply with this part.

Sec. 655.82 Compliance as a condition of financial assistance.

(a) General. A recipient may not be eligible for Federal financial assistance under 49 U.S.C. 5307, 5309, or 5311 or under 23 U.S.C. 103(e)(4), if a recipient fails to establish and implement an anti-drug and alcohol misuse program as required by this part. Failure to certify compliance with these requirements, as specified in Sec. 655.83, may result in the suspension of a grantee's eligibility for Federal funding.

(b) Criminal violation. A recipient is subject to criminal sanctions and fines for false statements or misrepresentations under 18 U.S.C. 1001.

(c) State's role. Each State shall certify compliance on behalf of its 49 U.S.C. 5307, 5309, 5311 or 23 U.S.C. 103(e)(4) subrecipients, as applicable. In so certifying, the State shall ensure that each subrecipient is complying with the requirements of this part. A section 5307, 5309, 5311 or 103(e)(4) subrecipient, through the administering State, is subject to suspension of funding from the State if such subrecipient is not in compliance with this part.

Sec. 655.83 Requirement to certify compliance.

(a) A recipient of FTA financial assistance shall annually certify compliance, as set forth in Sec. 655.82, to the applicable FTA Regional Office.

(b) A certification must be authorized by the organization's governing board or other authorizing official, and must be signed by a party specifically authorized to do so.

(c) A recipient will be ineligible for further FTA financial assistance if the recipient fails to establish and implement an anti-drug and alcohol misuse program in accordance with this part.

(d) FTA may determine that a recipient, who fails to comply with the USCG chemical and alcohol testing requirements, shall be in noncompliance with the alcohol misuse and controlled substances testing requirements of this part. A finding of noncompliance by FTA may lead to the suspension of eligibility for Federal public transportation funding.

[66 FR 42002, Aug. 9, 2001, as amended at 71 FR 69198, Nov. 30, 2006]

ATTACHMENT F-3

P R O T O C O L

Miami- Dade County Employee's Medical Assessment and Testing Procedures

PART 382--CONTROLLED SUBSTANCES AND ALCOHOL USE AND TESTING

[Code of Federal Regulations]
[Title 49, Volume 5]
[Revised as of October 1, 2009]
From the U.S. Government Printing Office via GPO Access
[CITE: 49CFR382]

[Page 169-187]

TITLE 49--TRANSPORTATION

CHAPTER III--FEDERAL MOTOR CARRIER SAFETY ADMINISTRATION, DEPARTMENT OF TRANSPORTATION

PART 382_CONTROLLED SUBSTANCES AND ALCOHOL USE AND TESTING--Table of Contents

Subpart A_General

Sec.
382.101 Purpose
382.103 Applicability.
382.105 Testing procedures.
382.107 Definitions.
382.109 Preemption of State and local laws.
382.111 Other requirements imposed by employers.
382.113 Requirements for notice.
382.115 Starting date for testing programs.
382.117 Public interest exclusion.
382.119 Stand-down waiver provision.
382.121 Employee admission of alcohol and controlled substances use.

Subpart B_Prohibitions

382.201 Alcohol concentration.
382.205 On-duty use.
382.207 Pre-duty use.
382.209 Use following an accident.

[[Page 170]]

382.211 Refusal to submit to a required alcohol or controlled substances test.
382.213 Controlled substances use.
382.215 Controlled substances testing.

Subpart C_Tests Required

382.301 Pre-employment testing.
382.303 Post-accident testing.
382.305 Random testing.
382.307 Reasonable suspicion testing.
382.309 Return-to-duty testing.
382.311 Follow-up testing.

Subpart D_Handling of Test Results, Record Retention, and Confidentiality

382.401 Retention of records.
382.403 Reporting of results in a management information system.
382.405 Access to facilities and records.
382.407 Medical review officer notifications to the employer.
382.409 Medical review officer record retention for controlled substances.
382.411 Employer notifications.
382.413 Inquiries for alcohol and controlled substances information from previous employers.

Subpart E_Consequences for Drivers Engaging in Substance Use-Related Conduct

382.501 Removal from safety-sensitive function.
382.503 Required evaluation and testing.
382.505 Other alcohol-related conduct.
382.507 Penalties.

Subpart F_Alcohol Misuse and Controlled Substances Use Information, Training, and Referral

382.601 Employer obligation to promulgate a policy on the misuse of alcohol and use of controlled substances.
382.603 Training for supervisors.
382.605 Referral, evaluation, and treatment.

Authority: 49 U.S.C. 31133, 31136, 31301 et seq., 31502; and 49 CFR 1.73.

Source: 66 FR 43103, Aug. 17, 2001, unless otherwise noted.

Subpart A_General

Sec. 382.101 Purpose.

The purpose of this part is to establish programs designed to help prevent accidents and injuries resulting from the misuse of alcohol or use of controlled substances by drivers of commercial motor vehicles.

Sec. 382.103 Applicability.

(a) This part applies to every person and to all employers of such persons who operate a commercial motor vehicle in commerce in any State, and is subject to:

(1) The commercial driver's license requirements of part 383 of this subchapter;

(2) The Licencia Federal de Conductor (Mexico) requirements; or

(3) The commercial drivers license requirements of the Canadian National Safety Code.

(b) 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.

(c) The exceptions contained in Sec. 390.3(f) of this subchapter do not apply to this part. The employers and drivers identified in Sec. 390.3(f) of this subchapter must comply with the requirements of this part, unless otherwise specifically provided in paragraph (d) of this section.

(d) Exceptions. This part shall not apply to employers and their drivers:

(1) Required to comply with the alcohol and/or controlled substances testing requirements of part 655 of this title (Federal Transit Administration alcohol and controlled substances testing regulations); or

(2) Who a State must waive from the requirements of part 383 of this subchapter. These individuals include active duty military personnel; members of the reserves; and members of the national guard on active duty, including personnel on full-time national guard duty, personnel on part-time national guard training and national guard military technicians (civilians who are required to wear military uniforms), and active duty U.S. Coast Guard personnel; or

(3) Who a State has, at its discretion, exempted from the requirements of part 383 of this subchapter. These individuals may be:

[[Page 171]]

(i) Operators of a farm vehicle which is:

(A) Controlled and operated by a farmer;

(B) Used to transport either agricultural products, farm machinery, farm supplies, or both to or from a farm;

(C) Not used in the operations of a common or contract motor

carrier; and

(D) Used within 241 kilometers (150 miles) of the farmer's farm.

(ii) Firefighters or other persons who operate commercial motor vehicles which are necessary for the preservation of life or property or the execution of emergency governmental functions, are equipped with audible and visual signals, and are not subject to normal traffic regulation.

Sec. 382.105 Testing procedures.

Each employer shall ensure that all alcohol or controlled substances testing conducted under this part complies with the procedures set forth in part 40 of this title. The provisions of part 40 of this title that address alcohol or controlled substances testing are made applicable to employers by this part.

Sec. 382.107 Definitions.

Words or phrases used in this part are defined in Sec. Sec. 386.2 and 390.5 of this subchapter, and Sec. 40.3 of this title, except as provided in this section--

Actual knowledge for the purpose of subpart B of this part, 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 Sec. 382.121. Direct observation as used in this definition means observation of alcohol or controlled substances use and does not include observation of employee behavior or physical characteristics sufficient to warrant reasonable suspicion testing under Sec. 382.307.

Alcohol means the intoxicating agent in beverage alcohol, ethyl alcohol, or other low molecular weight alcohols including methyl and isopropyl alcohol.

Alcohol concentration (or content) means the alcohol in a volume of breath expressed in terms of grams of alcohol per 210 liters of breath as indicated by an evidential breath test under this part.

Alcohol use means the drinking or swallowing of any beverage, liquid mixture or preparation (including any medication), containing alcohol.

Commerce means:

(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

(2) Trade, traffic, and transportation in the United States which affects any trade, traffic, and transportation described in paragraph (1) of this definition.

Commercial motor vehicle means a motor vehicle or combination of motor vehicles used in commerce to transport passengers or property if the vehicle--

(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

(2) Has a gross vehicle weight rating of 11,794 or more kilograms (26,001 or more pounds); or

(3) Is designed to transport 16 or more passengers, including the driver; or

(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 (49 U.S.C. 5103(b)) and which require the motor vehicle to be placarded under the Hazardous Materials Regulations (49 CFR part 172, subpart F).

Confirmation (or confirmatory) drug test means a second analytical procedure performed on a urine specimen to identify and quantify the presence of a specific drug or drug metabolite.

Confirmation (or confirmatory) validity test means a second test performed on a urine specimen to further support a validity test result.

Confirmed drug test means a confirmation test result received by an MRO from a laboratory.

[[Page 172]]

Consortium/Third party administrator (C/TPA) means 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/TPAs are not ``employers" for purposes of this part.

Controlled substances mean those substances identified in Sec. 40.85 of this title.

Designated employer representative (DER) is an individual identified by the employer as able to receive communications and test results from service agents and who is authorized to take immediate actions 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.

Disabling damage means damage which precludes departure of a motor vehicle from the scene of the accident in its usual manner in daylight after simple repairs.

(1) Inclusions. Damage to motor vehicles that could have been driven, but would have been further damaged if so driven.

(2) Exclusions. (i) Damage which can be remedied temporarily at the

scene of the accident without special tools or parts.

(ii) Tire disablement without other damage even if no spare tire is available.

(iii) Headlight or taillight damage.

(iv) Damage to turn signals, horn, or windshield wipers which make them inoperative.

DOT Agency means an agency (or ``operating administration'') of the United States Department of Transportation administering regulations requiring alcohol and/or drug testing (14 CFR parts 61, 63, 65, 121, and 135; 49 CFR parts 199, 219, 382, and 655), in accordance with part 40 of this title.

Driver means 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.

Employer means 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, as used in this part, 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 of this part.

Licensed medical practitioner means 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.

Performing (a safety-sensitive function) means 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.

Positive rate for random drug testing means the number of verified positive results for random drug tests conducted under this part plus the number of refusals of random drug tests required by this part, divided by the total number of random drug tests results (i.e., positives, negatives, and refusals) under this part.

Refuse to submit (to an alcohol or controlled substances test) means that a driver:

(1) Fail to appear for any test (except a pre-employment test) within a reasonable time, as determined by the employer, consistent with applicable DOT agency regulations, after being directed to do so by the employer. This includes the failure of an employee (including an owner-operator) to appear for a test when called by a C/TPA (see Sec. 40.61(a) of this title);

[[Page 173]]

(2) Fail to remain at the testing site until the testing process is complete. Provided, that an employee who leaves the testing site before

the testing process commences (see Sec. 40.63(c) of this title) a pre-employment test is not deemed to have refused to test;

(3) Fail to provide a urine specimen for any drug test required by this part or DOT agency regulations. Provided, that an employee who does not provide a urine specimen because he or she has left the testing site before the testing process commences (see Sec. 40.63(c) of this title) for a pre-employment test is not deemed to have refused to test;

(4) In the case of a directly observed or monitored collection in a drug test, fails to permit the observation or monitoring of the driver's provision of a specimen (see Sec. Sec. 40.67(l) and 40.69(g) of this title);

(5) Fail to provide a sufficient amount of urine when directed, and it has been determined, through a required medical evaluation, that there was no adequate medical explanation for the failure (see Sec. 40.193(d)(2) of this title);

(6) Fail or declines to take a second test the employer or collector has directed the driver to take;

(7) Fail to undergo a medical examination or evaluation, as directed by the MRO as part of the verification process, or as directed by the DER under Sec. 40.193(d) of this title. 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;

(8) Fail to cooperate with any part of the testing process (e.g., refuse to empty pockets when so directed by the collector, behave in a confrontational way that disrupts the collection process); or

(9) Is reported by the MRO as having a verified adulterated or substituted test result.

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) 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;

(2) All time inspecting equipment as required by Sec. Sec. 392.7 and 392.8 of this subchapter or otherwise inspecting, servicing, or conditioning any commercial motor vehicle at any time;

(3) All time spent at the driving controls of a commercial motor vehicle in operation;

(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 Sec. 393.76 of this subchapter);

(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

(6) All time repairing, obtaining assistance, or remaining in attendance upon a disabled vehicle.

Screening test (or initial test) means:

(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.

(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.

Stand-down means 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 results.

Violation rate for random alcohol testing means the number of 0.04 and above random alcohol confirmation test results conducted under this part plus the number of refusals of random alcohol tests required by this part, divided by the total number of random alcohol

[[Page 174]]

screening tests (including refusals) conducted under this part.

[66 FR 43103, Aug. 17, 2001, as amended at 68 FR 75458, Dec. 31, 2003]

Sec. 382.109 Preemption of State and local laws.

(a) Except as provided in paragraph (b) of this section, this part preempts any State or local law, rule, regulation, or order to the extent that:

(1) Compliance with both the State or local requirement in this part is not possible; or

(2) Compliance with the State or local requirement is an obstacle to the accomplishment and execution of any requirement in this part.

(b) This part shall not 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.

Sec. 382.111 Other requirements imposed by employers.

Except as expressly provided in this part, nothing in this part 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.

Sec. 382.113 Requirement for notice.

Before performing each alcohol or controlled substances test under this part, each employer shall notify a driver that the alcohol or controlled substances test is required by this part. No employer shall falsely represent that a test is administered under this part.

Sec. 382.115 Starting date for testing programs.

(a) All domestic-domiciled employers must implement the requirements of this part on the date the employer begins commercial motor vehicle operations.

(b) 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.

Sec. 382.117 Public interest exclusion.

No employer shall use the services of a service agent who is subject to public interest exclusion in accordance with 49 CFR part 40, Subpart R.

Sec. 382.119 Stand-down waiver provision.

(a) Employers are prohibited from standing employees down, except consistent with a waiver from the Federal Motor Carrier Safety Administration as required under this section.

(b) An employer subject to this part who seeks a waiver from the prohibition against standing down an employee before the MRO has completed the verification process shall follow the procedures in 49 CFR 40.21. The employer must send a written request, which includes all of the information required by that section to the Administrator, Federal Motor Carrier Safety Administration, 1200 New Jersey Ave., SE., Washington, DC 20590-0001.

(c) The final decision whether to grant or deny the application for a waiver will be made by the Administrator or the Administrator's designee.

(d) After a decision is signed by the Administrator or the Administrator's designee, the employer will be sent a copy of the decision, which will include the terms and conditions for the waiver or the reason for denying the application for a waiver.

(e) Questions regarding waiver applications should be directed to the Federal Motor Carrier Safety Administration, Office of Enforcement and Compliance (MC-EC), 1200 New Jersey Ave., SE., Washington, DC 20590-0001.

[66 FR 43103, Aug. 17, 2001, as amended at 72 FR 55700, Oct. 1, 2007]

Sec. 382.121 Employee admission of alcohol and controlled substances use.

(a) Employees who admit to alcohol misuse or controlled substances use are not subject to the referral, evaluation and treatment requirements of this part and part 40 of this title, provided that:

(1) The admission is in accordance with a written employer-established voluntary self-identification program or policy that meets the requirements of paragraph (b) of this section;

[[Page 175]]

(2) The driver does not self-identify in order to avoid testing under the requirements of this part;

(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

(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.

(b) A qualified voluntary self-identification program or policy must contain the following elements:

(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 (a) of this section;

(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;

(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;

(4) It must ensure that:

(i) 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

(ii) 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

(5) It may incorporate employee monitoring and include non-DOT follow-up testing.

Sec. 382.201 Alcohol concentration.

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.

Sec. 382.205 On-duty use.

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.

Sec. 382.207 Pre-duty use.

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.

Sec. 382.209 Use following an accident.

No driver required to take a post-accident alcohol test under Sec. 382.303 shall use alcohol for eight hours following the accident, or until he/she undergoes a post-accident alcohol test, whichever occurs first.

Sec. 382.211 Refusal to submit to a required alcohol or controlled substances test.

No driver shall refuse to submit to a post-accident alcohol or controlled substances test required under Sec. 382.303, a random alcohol or controlled substances test required under Sec. 382.305, a reasonable suspicion alcohol or controlled substances test required under Sec. 382.307, or a follow-up alcohol or controlled substances test required under Sec. 382.311. No employer shall permit a driver who refuses to submit to such tests to perform or continue to perform safety-sensitive functions.

Sec. 382.213 Controlled substances use.

(a) 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 Sec. 382.107, who has advised the driver that the substance will not adversely affect the driver's ability to safely operate a commercial motor vehicle.

(b) 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.

(c) An employer may require a driver to inform the employer of any therapeutic drug use.

Sec. 382.215 Controlled substances testing.

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.

Subpart C_Tests Required

Sec. 382.301 Pre-employment testing.

(a) 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 (b) of this section. No employer shall allow a driver, who the employer intends to hire or use, to perform safety-sensitive functions unless the employer has received a controlled substances test result from the MRO or C/TPA indicating a verified negative test result for that driver.

(b) An employer is not required to administer a controlled substances test required by paragraph (a) of this section if:

(1) The driver has participated in a controlled substances testing program that meets the requirements of this part within the previous 30 days; and

(2) While participating in that program, either:

(i) Was tested for controlled substances within the past 6 months (from the date of application with the employer), or

(ii) Participated in the random controlled substances testing program for the previous 12 months (from the date of application with the employer); and

(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.

(c)(1) An employer who exercises the exception in paragraph (b) of this section 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:

(i) Name(s) and address(es) of the program(s).

(ii) Verification that the driver participates or participated in the program(s).

(iii) Verification that the program(s) conforms to part 40 of this title.

(iv) Verification that the driver is qualified under the rules of this part, including that the driver has not refused to be tested for controlled substances.

(v) The date the driver was last tested for controlled substances.

(vi) The results of any tests taken within the previous six months and any other violations of subpart B of this part.

(2) An employer who uses, but does not employ a driver more than once a year to operate commercial motor vehicles must obtain the information in paragraph (c)(1) of this section at least once every six months. The records prepared under this paragraph shall be maintained in accordance with Sec. 382.401. If the employer cannot verify that the driver is participating in a controlled substances testing program in accordance with this part and part 40 of this

[[Page 177]]

title, the employer shall conduct a pre-employment controlled substances test.

(d) An employer may, but is not required to, conduct pre-employment alcohol testing under this part. If an employer chooses to conduct pre-employment alcohol testing, it must comply with the following requirements:

(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).

(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) 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.

(4) It must conduct all pre-employment alcohol tests using the alcohol testing procedures of 49 CFR part 40 of this title.

(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.

Sec. 382.303 Post-accident testing.

(a) As soon as practicable following an occurrence involving a commercial motor vehicle operating on a public road in commerce, each employer shall test for alcohol for each of its surviving drivers:

(1) Who was performing safety-sensitive functions with respect to the vehicle, if the accident involved the loss of human life; or

(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, if the accident involved:

(i) Bodily injury to any person who, as a result of the injury, immediately receives medical treatment away from the scene of the accident; or

(ii) 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.

(b) As soon as practicable following an occurrence involving a commercial motor vehicle operating on a public road in commerce, each employer shall test for controlled substances for each of its surviving drivers:

(1) Who was performing safety-sensitive functions with respect to the vehicle, if the accident involved the loss of human life; or

(2) Who receives a citation within thirty-two hours of the occurrence under State or local law for a moving traffic violation arising from the accident, if the accident involved:

(i) Bodily injury to any person who, as a result of the injury, immediately receives medical treatment away from the scene of the accident; or

(ii) 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.

(c) The following table notes when a post-accident test is required to be conducted by paragraphs (a)(1), (a)(2), (b)(1), and (b)(2) of this section:

Table for Sec. 382.303(a) and (b)

Type of accident involved	Citation issued to the CMV driver	Test must be performed by employer
Human fatality.....		

YES YES
NO YES

ii. Bodily injury with immediate medical treatment away from the scene.....
YES YES
NO NO

iii. Disabling damage to any motor vehicle requiring tow away.....
YES YES
NO NO

[[Page 178]]

(d)(1) 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.

(2) 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.

(e) 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.

(f) An 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.

(g)(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.

(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.

(h) Exception. This section does not apply to:

(1) An occurrence involving only boarding or alighting from a stationary motor vehicle; or

(2) An occurrence involving only the loading or unloading of cargo; or

(3) An occurrence in the course of the operation of a passenger car or a multipurpose passenger vehicle (as defined in Sec. 571.3 of this title) 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 Sec. 177.823 of this title.

Sec. 382.305 Random testing.

(a) Every employer shall comply with the requirements of this section. Every driver shall submit to random alcohol and controlled substance testing as required in this section.

(b)(1) Except as provided in paragraphs (c) through (e) of this section, the minimum annual percentage rate for random alcohol testing shall be 10 percent of the average number of driver positions.

(2) Except as provided in paragraphs (f) through (h) of this section, the minimum annual percentage rate for random controlled substances testing shall be 50 percent of the average number of driver positions.

(c) 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 Sec. 382.403. 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,

[[Page 179]]

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 new 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.

(d)(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 Sec. 382.403 for two consecutive calendar years indicate that the violation rate is less than 0.5 percent.

(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 Sec. 382.403 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.

(e)(1) When the minimum annual percentage rate for random alcohol testing is 10 percent, and the data received under the reporting requirements of Sec. 382.403 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.

(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 Sec. 382.403 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.

(f) 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 Sec. 382.403. 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 new minimum annual percentage rate for 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.

(g) 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 Sec. 382.403 for two consecutive calendar years indicate that the positive rate is less than 1.0 percent.

(h) When the minimum annual percentage rate for random controlled substances testing is 25 percent, and the data received under the reporting requirements of Sec. 382.403 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.

(i)(1) 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.

[[Page 180]]

(2) Each driver selected for random alcohol and controlled substances testing under the selection process used, shall have an equal chance of being tested each time selections are made.

(3) Each driver selected for testing shall be tested during the selection period.

(j)(1)To calculate the total number of covered drivers eligible for random testing throughout the year, as an employer, you must add the total number of covered drivers eligible for testing during each random testing period for the year and divide that total by the number of random testing periods. Covered employees, and only covered employees, are to be in an employer's random testing pool, and all covered drivers must be in the random pool. If you are an employer conducting random testing more often than once per month (e.g., daily, weekly, bi-weekly) you do not need to compute this total number of covered drivers rate more than on a once per month basis.

(2) As an employer, you may use a service agent (e.g., a C/TPA) to perform random selections for you, and your covered drivers may be part of a larger random testing pool of covered employees. However, you must ensure that the service agent you use is testing at the appropriate percentage established for your industry and that only covered employees are in the random testing pool.

(k)(1) Each employer shall ensure that random alcohol and controlled substances tests conducted under this part are unannounced.

(2) Each employer shall ensure that the dates for administering random alcohol and controlled substances tests conducted under this part are spread reasonably throughout the calendar year.

(l) Each employer shall require that each driver who is notified of selection for random alcohol and/or controlled substances testing proceeds to the test site immediately; provided, however, that 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.

(m) 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.

(n) 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 same 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.

(o) If an 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--

(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

(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.

[66 FR 43103, Aug. 17, 2001, as amended at 67 FR 61821, Oct. 2, 2002; 68 FR 75459, Dec. 31, 2003]

Sec. 382.307 Reasonable suspicion testing.

(a) An employer shall require a driver to submit to an alcohol test when the employer has reasonable suspicion to believe that the driver has violated the prohibitions of subpart B of this part 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.

(b) An employer shall require a driver to submit to a controlled substances test when the employer has reasonable suspicion to believe that the driver has

[[Page 181]]

violated the prohibitions of subpart B of this part 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 withdrawal effects of controlled substances.

(c) The required observations for alcohol and/or controlled substances reasonable suspicion testing shall be made by a supervisor or company official who is trained in accordance with Sec. 382.603. The person who makes the determination that reasonable suspicion exists to conduct an alcohol test shall not conduct the alcohol test of the driver.

(d) Alcohol testing is authorized by this section only if the observations required by paragraph (a) of this section 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.

(e)(1) If an alcohol test required by this section is not administered within two hours following the determination under paragraph (a) of this section, 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 (a) of this section, the employer shall cease attempts to administer an alcohol test and shall state in the record the reasons for not administering the test.

(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 behavioral, speech, and performance indicators of alcohol misuse, nor shall an employer permit the driver to perform or continue to perform safety-sensitive functions, until:

(i) An alcohol test is administered and the driver's alcohol concentration measures less than 0.02; or

(ii) Twenty four hours have elapsed following the determination under paragraph (a) of this section that there is reasonable suspicion to believe that the driver has violated the prohibitions in this part concerning the use of alcohol.

(3) Except as provided in paragraph (e)(2) of this section, no employer shall take any 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.

(f) A written record shall be made of the observations leading to an alcohol or controlled substances reasonable suspicion test, and signed by the supervisor or company official who made the observations, within 24 hours of the observed behavior or before the results of the alcohol or controlled substances tests are released, whichever is earlier.

Sec. 382.309 Return-to-duty testing.

The requirements for return-to-duty testing must be performed in accordance with 49 CFR part 40, Subpart O.

Sec. 382.311 Follow-up testing.

The requirements for follow-up testing must be performed in accordance with 49 CFR part 40, Subpart O.

Subpart D_Handling of Test Results, Records Retention, and Confidentiality

Sec. 382.401 Retention of records.

(a) General requirement. 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.

[[Page 182]]

(b) Period of retention. Each employer shall maintain the records in accordance with the following schedule:

(1) Five years. The following records shall be maintained for a minimum of five years:

(i) Records of driver alcohol test results indicating an alcohol concentration of 0.02 or greater,

(ii) Records of driver verified positive controlled substances test results,

(iii) Documentation of refusals to take required alcohol and/or controlled substances tests,

(iv) Driver evaluation and referrals,

(v) Calibration documentation,

(vi) Records related to the administration of the alcohol and controlled substances testing programs, and

(vii) A copy of each annual calendar year summary required by Sec. 382.403.

(2) Two years. Records related to the alcohol and controlled substances collection process (except calibration of evidential breath testing devices).

(3) One year. Records of negative and canceled controlled substances test results (as defined in part 40 of this title) and alcohol test results with a concentration of less than 0.02 shall be maintained for a minimum of one year.

(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.

(c) Types of records. 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.

(1) Records related to the collection process:

(i) Collection logbooks, if used;

(ii) Documents relating to the random selection process;

(iii) Calibration documentation for evidential breath testing devices;

(iv) Documentation of breath alcohol technician training;

(v) Documents generated in connection with decisions to administer reasonable suspicion alcohol or controlled substances tests;

(vi) Documents generated in connection with decisions on post-accident tests;

(vii) 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

(viii) A copy of each annual calendar year summary as required by Sec. 382.403.

(2) Records related to a driver's test results:

(i) The employer's copy of the alcohol test form, including the results of the test;

(ii) The employer's copy of the controlled substances test chain of custody and control form;

(iii) Documents sent by the MRO to the employer, including those required by part 40, subpart G, of this title;

(iv) Documents related to the refusal of any driver to submit to an alcohol or controlled substances test required by this part;

(v) Documents presented by a driver to dispute the result of an alcohol or controlled substances test administered under this part; and

(vi) Documents generated in connection with verifications of prior employers' alcohol or controlled substances test results that the employer:

(A) Must obtain in connection with the exception contained in Sec. 382.301, and

(B) Must obtain as required by Sec. 382.413.

(3) Records related to other violations of this part.

(4) Records related to evaluations:

(i) Records pertaining to a determination by a substance abuse professional concerning a driver's need for assistance; and

(ii) Records concerning a driver's compliance with recommendations of the substance abuse professional.

(5) Records related to education and training:

(i) Materials on alcohol misuse and controlled substance use awareness, including a copy of the employer's policy on alcohol misuse and controlled substance use;

[[Page 183]]

(ii) Documentation of compliance with the requirements of Sec. 382.601, including the driver's signed receipt of education materials;

(iii) 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;

(iv) Documentation of training for breath alcohol technicians as required by Sec. 40.213(a) of this title; and

(v) Certification that any training conducted under this part complies with the requirements for such training.

(6) Administrative records related to alcohol and controlled substances testing:

(i) Agreements with collection site facilities, laboratories, breath alcohol technicians, screening test technicians, medical review officers, consortia, and third party service providers;

(ii) Names and positions of officials and their role in the employer's alcohol and controlled substances testing program(s);

(iii) Semi-annual laboratory statistical summaries of urinalysis required by Sec. 40.111(a) of this title; and

(iv) The employer's alcohol and controlled substances testing policy and procedures.

(d) Location of records. All records required by this part shall be maintained as required by Sec. 390.31 of this subchapter 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 Federal Motor Carrier Safety Administration.

(e) OMB control number. (1) The information collection requirements of this part have been reviewed by the Office of Management and Budget pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.) and have been assigned OMB control number 2126-0012.

(2) The information collection requirements of this part are found in the following sections: Sections 382.105, 382.113, 382.301, 382.303, 382.305, 382.307, 382.401, 382.403, 382.405, 382.409, 382.411, 382.601, 382.603.

[66 FR 43103, Aug. 17, 2001, as amended at 67 FR 61821, Oct. 2, 2002; 68 FR 75459, Dec. 31, 2003]

Sec. 382.403 Reporting of results in a management information system.

(a) An employer shall prepare and maintain a summary of the results of its alcohol and controlled substances testing programs performed under this part 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.

(b) If an employer is notified, during the month of January, of a request by the Federal Motor Carrier Safety Administration 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 employer must use the Management Information System (MIS) form and instructions as required by 49 CFR part 40 (at Sec. 40.26 and appendix H to part 40). The employer may also use the electronic version of the MIS form provided by the DOT. The Administrator may designate means (e.g., electronic program transmitted via the Internet), other than hard-copy, for MIS form submission. For information on the electronic version of the form, see: http://www.fmcsa.dot.gov/safetyprogs/drugs/engtesting.htm.

(c) 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.

(d) If you have a covered employee who performs multi-DOT agency functions (e.g., an employee drives a commercial motor vehicle and performs pipeline maintenance duties for the same employer), count the employee

[[Page 184]]

only on the MIS report for the DOT agency under which he or she is randomly tested. Normally, this will be the DOT agency under which the employee performs more than 50% of his or her duties. Employers may have to explain the testing data for these employees in the event of a DOT agency inspection or audit.

(e) A service agent (e.g., Consortia/Third party administrator as defined in 49 CFR 382.107) may prepare the MIS report on behalf of an employer. However, a company official (e.g., Designated employer representative) must certify the accuracy and completeness of the MIS report, no matter who prepares it.

[66 FR 43103, Aug. 17, 2001, as amended at 68 FR 75459, Dec. 31, 2003]

Sec. 382.405 Access to facilities and records.

(a) 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 Sec. 382.401.

(b) 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.

(c) 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.

(d) 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.

(e) 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.

(f) 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.

(g) An employer may disclose information required to be maintained under this part pertaining to a driver to the decision maker in a lawsuit, grievance, or administrative 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 Sec. 40.323(a)(2) of this title.

(h) 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 Sec. 40.321(b) of this title.

Sec. 382.407 Medical review officer notifications to the employer.

Medical review officers shall report the results of controlled substances tests to employers in accordance with the requirements of part 40, Subpart G, of this title.

Sec. 382.409 Medical review officer record retention for controlled substances.

(a) A medical review officer 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.

(b) A medical review officer or third party administrator shall maintain all dated records and notifications, identified by individual, for a minimum of one year for negative and canceled controlled substances test results.

(c) No person may obtain the individual controlled substances test results retained by a medical review officer or third party administrator, and no medical review officer 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 (c) shall prohibit a medical review officer or third party administrator 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 part 40, Subpart G, of this title.

Sec. 382.411 Employer notifications.

(a) An employer shall notify a driver of the results of a pre-employment controlled substances 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. An 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.

(b) The designated employer representative 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.

(c) The designated employer representative shall immediately notify the medical review officer that the driver has been notified to contact the medical review officer within 72 hours.

Sec. 382.413 Inquiries for alcohol and controlled substances information from previous employers.

Employers shall request alcohol and controlled substances information from previous employers in accordance with the requirements

of Sec. 40.25 of this title.

Subpart E_Consequences for Drivers Engaging in Substance Use-Related Conduct

Sec. 382.501 Removal from safety-sensitive function.

(a) Except as provided in subpart F of this part, no driver shall perform safety-sensitive functions, including driving a commercial motor vehicle, if the driver has engaged in conduct prohibited by subpart B of this part or an alcohol or controlled substances rule of another DOT agency.

(b) 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.

(c) For purposes of this subpart, commercial motor vehicle means a commercial motor vehicle in commerce as defined in Sec. 382.107, and a commercial motor vehicle in interstate commerce as defined in part 390 of this subchapter.

Sec. 382.503 Required evaluation and testing.

No driver who has engaged in conduct prohibited by subpart B of this part shall perform safety-sensitive functions, including driving a commercial motor vehicle, unless the driver has met the requirements of part 40, subpart O, of this title. No employer shall permit a driver who has engaged in conduct prohibited by subpart B of this part to perform safety-sensitive functions, including driving a commercial motor vehicle, unless the driver has met the requirements of part 40, subpart O, of this title.

[[Page 186]]

Sec. 382.505 Other alcohol-related conduct.

(a) No driver tested under the provisions of subpart C of this part 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.

(b) Except as provided in paragraph (a) of this section, 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.

Sec. 382.507 Penalties.

Any employer or driver who violates the requirements of this part shall be subject to the civil and/or criminal penalty provisions of 49 U.S.C. 521(b). In addition, any employer or driver who violates the requirements of 49 CFR part 40 shall be subject to the civil and/or criminal penalty provisions of 49 U.S.C. 521(b).

Subpart F_Alcohol Misuse and Controlled Substances Use Information, Training, and Referral

Sec. 382.601 Employer obligation to promulgate a policy on the misuse of alcohol and use of controlled substances.

(a) General requirements. Each employer shall provide educational materials that explain the requirements of this part and the employer's policies and procedures with respect to meeting these requirements.

(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) Each employer shall provide written notice to representatives of employee organizations of the availability of this information.

(b) Required content. The materials to be made available to drivers shall include detailed discussion of at least the following:

(1) The identity of the person designated by the employer to answer driver questions about the materials;

(2) The categories of drivers who are subject to the provisions of this part;

(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;

(4) Specific information concerning driver conduct that is prohibited by this part;

(5) The circumstances under which a driver will be tested for alcohol and/or controlled substances under this part, including post-accident testing under Sec. 382.303(d);

(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 Sec. 382.303(d);

(7) The requirement that a driver submit to alcohol and controlled substances tests administered in accordance with this part;

(8) An explanation of what constitutes a refusal to submit to an alcohol or controlled substances test and the attendant consequences;

(9) The consequences for drivers found to have violated subpart B of this part, including the requirement that the driver be removed immediately from safety-sensitive functions, and the procedures under part 40, subpart O, of this title;

(10) The consequences for drivers found to have an alcohol concentration of 0.02 or greater but less than 0.04;

[[Page 187]]

(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.

(c) Optional provision. 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 this part. Any such additional policies or consequences must be clearly and obviously described as being based on independent authority.

(d) Certificate of receipt. Each employer shall ensure that each driver is required to sign a statement certifying that he or she has received a copy of these materials described in this section. Each employer shall maintain the original of the signed certificate and may provide a copy of the certificate to the driver.

Sec. 382.603 Training for supervisors.

Each 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 Sec. 382.307. The training shall include the physical, behavioral, speech, and performance indicators of probable alcohol misuse and use of controlled substances. Recurrent training for supervisory personnel is not required.

Sec. 382.605 Referral, evaluation, and treatment.

The requirements for referral, evaluation, and treatment must be performed in accordance with 49 CFR part 40, Subpart O.

256