REQUEST FOR PROPOSALS (RFP) 3-3068

MEDICAL CLINIC SERVICES

ORANGE COUNTY TRANSPORTATION AUTHORITY
550 South Main Street
P.O. Box 14184
Orange, CA 92863-1584
(714) 560-6282

Key RFP Dates

Issue Date:	**January 29, 2024**
Pre-Proposal Conference Date:	**February 7, 2024**
Question Submittal Date:	**February 9, 2024**
Proposal Submittal Date:	**February 26, 2024**
Interview Date:	**March 14, 2024**

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January 29, 2024

NOTICE OF REQUEST FOR PROPOSALS (RFP)

RFP 3-3068: "MEDICAL CLINIC SERVICES"

TO: ALL OFFERORS

FROM: ORANGE COUNTY TRANSPORTATION AUTHORITY

The Orange County Transportation Authority (Authority) invites proposals from qualified medical clinics specialized in Occupational Medicine and Therapy to provide medical clinic services.

The budget for this project is $673,000.00 for a three (3)-year initial term.

Please note that by submitting a Proposal, Offeror certifies that it is not subject to any Ukraine/Russia-related economic sanctions imposed by the State of California or the United States Government including, but not limited to, Presidential Executive Order Nos. 13660, 13661, 13662, 13685, and 14065. Any individual or entity that is the subject of any Ukraine/Russia-related economic sanction is not eligible to submit a Proposal. In submitting a Proposal, all Offerors agree to comply with all economic sanctions imposed by the State or U.S. Government.

Proposals must be submitted, electronically, through the following URL link: http://www.octa.net/Proposal Upload Link, at or before the deadline of **2:00 p.m. on February 26, 2024. The link has an upload file size limit of 80MB. Authority will not accept hard copy proposals for this RFP.**

Offerors are instructed to click the upload link, select "**RFP 3-3068**" from the drop-down menu, and follow the instructions as prompted to upload the proposal. The upload link will expire at the submittal deadline and will not allow proposals to be uploaded.

Should Offerors encounter technical issues with uploading the proposals via the link provided, Offerors are required to contact the Contract Administrator prior to the submission deadline. Proposals and supplemental information to proposals received after the date and time specified above will be rejected.

Firms interested in obtaining a copy of this RFP may do so by downloading the RFP from CAMM NET at https://cammnet.octa.net.

All firms interested in doing business with the Authority are required to register their business on-line at CAMM NET. The website can be found at https://cammnet.octa.net. From the site menu, click on CAMM NET to register.

To receive all further information regarding this RFP 3-3068, firms and subconsultants must be registered on CAMM NET with at least one of the following commodity codes for this solicitation selected as part of the vendor's on-line registration profile:

Category:	Commodity:
Security, Safety and Health Services	Drug Detection Services Health Services

A hybrid pre-proposal conference will be held on February 7, 2024 at 11:00 a.m.

For prospective Offerors who wish to join in-person/on-site, the pre-proposal conference will be held at the Authority's Administrative Office:

- 550 South Main Street, Orange, California, 92868
- Conference Room Number 09.

For prospective Offerors who wish to join via teleconference, please join or call-in using the following credentials:

- Click here to join the meeting
- or Call-in Number: 916-550-9867
- Conference ID: 325 460 378#

All prospective Offerors are encouraged to attend the pre-proposal conference.

The Authority has established March 14, 2024, as the date to conduct interviews and/or site visits. All prospective Offerors will be asked to keep this date available.

Offerors are encouraged to subcontract with small businesses to the maximum extent possible.

All Offerors will be required to comply with all applicable equal opportunity laws and regulations.

The award of this contract is subject to receipt of federal, state and/or local funds adequate to carry out the provisions of the proposed agreement including the identified Scope of Work.

SECTION I: INSTRUCTIONS TO OFFERORS

SECTION I. INSTRUCTIONS TO OFFERORS

A. PRE-PROPOSAL CONFERENCE

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- 550 South Main Street, Orange, California, 92868
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- Click here to join the meeting
- or Call-in Number: 916-550-9867
- Conference ID: 325 460 378#

All prospective Offerors are encouraged to attend the pre-proposal conference.

B. EXAMINATION OF PROPOSAL DOCUMENTS

By submitting a proposal, Offeror represents that it has thoroughly examined and become familiar with the work required under this RFP and that it is capable of performing quality work to achieve the Authority's objectives.

C. ADDENDA

The Authority reserves the right to revise the RFP documents. Any Authority changes to the requirements will be made by written addendum to this RFP. Any written addenda issued pertaining to this RFP shall be incorporated into the terms and conditions of any resulting Agreement. The Authority will not be bound to any modifications to or deviations from the requirements set forth in this RFP as the result of oral instructions. Offerors shall acknowledge receipt of addenda in their proposals. Failure to acknowledge receipt of Addenda may cause the proposal to be deemed non-responsive to this RFP and be rejected.

D. AUTHORITY CONTACT

All communication and/or contacts with Authority staff regarding this RFP are to be directed to the following Contract Administrator:

Jackie Le, Senior Contract Administrator
Contracts Administration and Materials Management Department
Phone: 714.560.5486
E-mail: jle@octa.net

Commencing on the date of the issuance of this RFP and continuing until award of the contract or cancellation of this RFP, no offeror, subcontractor, lobbyist or agent hired by the offeror shall have any contact or communications regarding this RFP with any Authority's staff; member of the evaluation committee for this RFP; or any contractor or consultant involved with the procurement, other than the Contract Administrator named above or unless expressly permitted by this RFP. Contact includes face-to-face, telephone, electronic mail (e-mail) or formal written communication. Any offeror, subcontractor, lobbyist or agent hired by the offeror that engages in such prohibited communications may result in disqualification of the offeror at the sole discretion of the Authority.

E. CLARIFICATIONS

1. Examination of Documents

Should an Offeror require clarifications of this RFP, the Offeror shall notify the Authority in writing in accordance with Section E.2. below. Should it be found that the point in question is not clearly and fully set forth, the Authority will issue a written addendum clarifying the matter which will be sent to all firms registered on CAMM NET under the commodity codes specified in this RFP.

2. Submitting Requests

a. All questions, including questions that could not be specifically answered at the pre-proposal conference, must be put in writing and received via e-mail at jle@octa.net no later than 5:00 p.m., on February 9, 2024.

b. Requests for clarifications, questions, and comments must be clearly labeled, "Written Questions RFP 3-3068," in the subject line of the e-mail. The Authority is not responsible for failure to respond to a request that has not been labeled as such.

3. Authority Responses

Responses from the Authority will be posted on CAMM NET no later than February 16, 2024. Offerors may download responses from CAMM NET at *https://cammnet.octa.net*, or request responses be sent via e-mail.

To receive e-mail notification of Authority responses when they are posted on CAMM NET, firms and subconsultants must be registered on CAMM NET with at least one of the following commodity codes for this solicitation selected as part of the vendor's on-line registration profile:

Category:	Commodity:
Security, Safety and Health Services	Drug Detection Services Health Services

Inquiries received after 5:00 p.m. on February 9, 2024 will not be responded to.

F. SUBMISSION OF PROPOSALS

1. Date and Time

Proposals must be submitted, electronically, through the following URL link: http://www.octa.net/Proposal Upload Link, at or before the deadline of **2:00 p.m. on February 26, 2024. The link has an upload file size limit of 80MB. Authority will not accept hard copy proposals for this RFP.**

Offerors are instructed to click the upload link, select "**RFP 3-3068**" from the drop-down menu, and follow the instructions as prompted to upload the proposal. The upload link will expire at the submittal deadline and will not allow proposals to be uploaded.

Should Offerors encounter technical issues with uploading the proposals via the link provided, Offerors are required to contact the Contract Administrator prior to the submission deadline. Proposals and supplemental information to proposals received after the date and time specified above will be rejected.

2. Acceptance of Proposals

a. The Authority reserves the right to accept or reject any and all proposals, or any item or part thereof, or to waive any informalities or irregularities in proposals.

b. The Authority reserves the right to withdraw or cancel this RFP at any time without prior notice and the Authority makes no representations that any contract will be awarded to any Offeror

responding to this RFP.

c. The Authority reserves the right to issue a new RFP for the project.

d. The Authority reserves the right to postpone proposal openings for its own convenience.

e. Each proposal will be received with the understanding that acceptance by the Authority of the proposal to provide the services described herein shall constitute a contract between the Offeror and Authority which shall bind the Offeror on its part to furnish and deliver at the prices given and in accordance with conditions of said accepted proposal and specifications.

f. The Authority reserves the right to investigate the qualifications of any Offeror, and/or require additional evidence of qualifications to perform the work.

g. Submitted proposals are not to be copyrighted.

G. PRE-CONTRACTUAL EXPENSES

The Authority shall not, in any event, be liable for any pre-contractual expenses incurred by Offeror in the preparation of its proposal. Offeror shall not include any such expenses as part of its proposal.

Pre-contractual expenses are defined as expenses incurred by Offeror in:

1. Preparing its proposal in response to this RFP;
2. Submitting that proposal to the Authority;
3. Negotiating with the Authority any matter related to this proposal; or
4. Any other expenses incurred by Offeror prior to date of award, if any, of the Agreement.

H. JOINT OFFERS

Where two or more firms desire to submit a single proposal in response to this RFP, they should do so on a prime-subcontractor basis rather than as a joint venture. The Authority intends to contract with a single firm and not with multiple firms doing business as a joint venture.

I. TAXES

Offerors' proposals are subject to State and Local sales taxes. However, the Authority is exempt from the payment of Federal Excise and Transportation Taxes. Offeror is responsible for payment of all taxes for any goods, services, processes and operations incidental to or involved in the contract.

J. PROTEST PROCEDURES

The Authority has on file a set of written protest procedures applicable to this solicitation that may be obtained by contacting the Contract Administrator responsible for this procurement. Any protests filed by an Offeror in connection with this RFP must be submitted in accordance with the Authority's written procedures.

K. CONTRACT TYPE

It is anticipated that the Agreement resulting from this solicitation, if awarded, will be a time and expense contract with fully burdened labor rates and anticipated expenses for work specified in the scope of work, included in the RFP as Exhibit A. The term of the Agreement will be for a three (3)-year initial term, with one two (2)-year option term.

L. CONFLICT OF INTEREST

All Offerors responding to this RFP must avoid organizational conflicts of interest which would restrict full and open competition in this procurement. An organizational conflict of interest means that due to other activities, relationships or contracts, an Offeror is unable, or potentially unable to render impartial assistance or advice to the Authority; an Offeror's objectivity in performing the work identified in the Scope of Work is or might be otherwise impaired; or an Offeror has an unfair competitive advantage. Conflict of Interest issues must be fully disclosed in the Offeror's proposal.

All Offerors must disclose in their proposal and immediately throughout the course of the evaluation process if they have hired or retained an advocate to lobby Authority staff or the Board of Directors on their behalf.

Offerors hired to perform services for the Authority are prohibited from concurrently acting as an advocate for another firm who is competing for a contract with the Authority, either as a prime or subcontractor.

M. CODE OF CONDUCT

All Offerors agree to comply with the Authority's Code of Conduct as it relates to Third-Party contracts which is hereby referenced and by this reference is incorporated herein. All Offerors agree to include these requirements in all of its subcontracts.

N. OWNERSHIP OF RECORDS/PUBLIC RECORDS ACT

All proposals and documents submitted in response to this RFP shall become the property of the Authority and a matter of public record pursuant to the California Public Records Act, Government Code sections 6250 et seq. (the "Act"). Offerors should familiarize themselves with the provisions of the Act requiring disclosure of

public information. Offerors are discouraged from marking their proposal documents as "confidential" or "proprietary."

If a Proposal does include "confidential" or "proprietary" markings and the Authority receives a request pursuant to the Act, the Authority will endeavor (but cannot guarantee) to notify the Offeror of such a request. In order to protect any information submitted within a Proposal, the Offeror must pursue, at its sole cost and expense, any and all appropriate legal action necessary to maintain the confidentiality of such information. The Authority generally does not consider pricing information, subcontractor lists, or key personnel, including resumes, as being exempt from disclosure under the Act. In no event shall the Authority or any of its officers, directors, employees, agents, representatives, or consultants be liable to a Offeror for the disclosure of any materials or information submitted in response to the RFP or by failing to notify a Offeror of a request seeking its Proposal. The Authority reserves the right to make an independent decision to disclose records and material.

Notwithstanding the above, all information regarding proposal responses will be held as confidential until such time as the evaluation has been completed; an award has been made by the Board of Directors or Authority Staff, as appropriate; and the contract has been fully negotiated.

O. STATEMENT OF ECONOMIC INTERESTS

The awarded Offeror (including designated employees and subconsultants) may be required to file Statements of Economic Interests (Form 700) in accordance with the Political Reform Act (Government Code section 81000 et seq.). This applies to individuals who make, participate in making, or act in a staff capacity for making governmental decisions. The Authority determines which individuals are required to file a Form 700, and if such determination is made, the individuals must file Form 700s with the Authority’s Clerk of the Board no later than 30 days after the execution of the Agreement, annually thereafter for the duration of the Agreement, and within 30 days of termination of the Agreement.

SECTION II: PROPOSAL CONTENT

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A. PROPOSAL FORMAT AND CONTENT

1. Format

Proposals should be typed with a standard 12-point font, double-spaced. Proposals should not include any unnecessarily elaborate or promotional materials. Proposals should not exceed fifty (50) pages in length, excluding any appendices, cover letters, resumes, or forms.

2. Letter of Transmittal

The Letter of Transmittal shall be addressed to Jackie Le, Senior Contract Administrator, and must, at a minimum, contain the following:

a. Identification of Offeror that will have contractual responsibility with the Authority. Identification shall include legal name of company, corporate address, telephone and fax number, and e-mail address. Include name, title, address, e-mail address, and telephone number of the contact person identified during period of proposal evaluation.

b. Identification of all proposed subcontractors including legal name of company, contact person's name and address, phone number and fax number, and e-mail address; relationship between Offeror and subcontractors, if applicable.

c. Acknowledgement of receipt of all RFP addenda, if any.

d. A statement to the effect that the proposal shall remain valid for a period of not less than 120 days from the date of submittal.

e. Signature of a person authorized to bind Offeror to the terms of the proposal.

f. Signed statement attesting that all information submitted with the proposal is true and correct.

3. Technical Proposal

a. Qualifications, Related Experience and References of Offeror

This section of the proposal should establish the ability of Offeror to satisfactorily perform the required work by reasons of: experience in performing work of a similar nature; demonstrated competence in the services to be provided; strength and stability of the firm; staffing

capability; work load; record of meeting schedules on similar projects; and supportive client references.

Offeror to:

(1) Provide a brief profile of the firm, including the types of services offered; the year founded; form of the organization (corporation, partnership, sole proprietorship); number, size and location of offices; and number of employees.

(2) Provide a general description of the firm's financial condition and identify any conditions (e.g., bankruptcy, pending litigation, planned office closures, impending merger) that may impede Offeror's ability to complete the project.

(3) Describe the firm's experience in performing work of a similar nature to that solicited in this RFP, and highlight the participation in such work by the key personnel proposed for assignment to this project.

(4) Identify subcontractors by company name, address, contact person, telephone number, e-mail, and project function. Describe Offeror's experience working with each subcontractor.

(5) Identify all firms hired or retained to provide lobbying or advocating services on behalf of the Offeror by company name, address, contact person, telephone number and e-mail address. This information is required to be provided by the Offeror immediately during the evaluation process, if a lobbyist or advocate is hired or retained.

(6) Provide as a minimum three (3) references for the projects cited as related experience, and furnish the name, title, address, telephone number, and e-mail address of the person(s) at the client organization who is most knowledgeable about the work performed. Offeror may also supply references from other work not cited in this section as related experience.

b. Proposed Staffing and Project Organization

This section of the proposal should establish the method, which will be used by the Offeror to manage the project, as well as identify key personnel assigned.

Offeror to:

(1) Provide education, experience, and applicable professional credentials of project staff; provide copies of current certifications/license for Medical Examiners.

(2) Identify key personnel proposed to perform the work in the specified tasks and include major areas of subcontract work. Include the person's name, current location, proposed position for this project, current assignment, level of commitment to that assignment, availability for this assignment and how long each person has been with the firm.

(3) Furnish brief resumes (not more than two [2] pages each) for the proposed Project Manager and other key personnel that includes education, experience, and applicable professional credentials that meet the minimum qualifications as specified in Exhibit A.

(4) Provide the number and type of employees available for the time frames listed in Exhibit A, Section II.A, paragraph 11.

(5) Provide physicians certified on the National Registry of Certified Medical Examiners. Include copies of current certifications/licenses for Medical Examiners.

(6) Include a project organization chart, which clearly delineates communication/reporting relationships among the project staff.

(7) Include a statement that key personnel will be available to the extent proposed for the duration of the project acknowledging that no person designated as "key" to the project shall be removed or replaced without the prior written concurrence of the Authority.

c. Work Plan

Offeror should provide a narrative, which addresses the Scope of Work, and shows Offeror's understanding of Authority's needs and requirements.

Offeror to:

(1) Describe the approach to completing the work specified in the Scope of Work. The approach to the work plan shall be of such detail to demonstrate the Offeror's ability to accomplish the project objectives and overall schedule.

(2) Outline sequentially the activities that would be undertaken in completing the work and specify who would perform them.

(3) Provide a Continuity of Service Plan detailing strategies for ensuring uninterrupted service delivery in the face of potential disruptions.

(4) Identify methods that Offeror will use to ensure quality control, as well as budget and schedule control for the project.

(5) Identify any special issues or problems that are likely to be encountered in this project and how the Offeror would propose to address them.

(6) Offeror is encouraged to propose enhancements or procedural or technical innovations to the Scope of Work that do not materially deviate from the objectives or required content of the project.

d. Exceptions/Deviations

State any technical and/or contractual exceptions and/or deviations from the requirements of this RFP, including the Authority's technical requirements and contractual terms and conditions set forth in the Scope of Work (Exhibit A) and Proposed Agreement (Exhibit C), using the form entitled "Proposal Exceptions and/or Deviations" included in this RFP. This Proposal Exceptions and/or Deviations form (Exhibit G) must be included in the original proposal submitted by the Offeror. If no technical or contractual exceptions and/or deviations are submitted as part of the original proposal, Offerors are deemed to have accepted the Authority's technical requirements and contractual terms and conditions set forth in the Scope of Work (Exhibit A) and Proposed Agreement (Exhibit C). Offerors will not be allowed to submit the Proposal Exceptions and/or Deviations form (Exhibit G) or any technical and/or contractual exceptions after the proposal submittal date identified in the RFP. Exceptions and/or deviations submitted after the proposal submittal date will not be reviewed by Authority.

All exceptions and/or deviations will be reviewed by the Authority and will be assigned a "pass" or "fail" status. Exceptions and deviations that "pass" do not mean that the Authority has accepted the change but that it is a potential negotiable issue. Exceptions and deviations that receive a "fail" status means that the requested change is not something that the Authority would consider a potential negotiable issue. Offerors that receive a "fail" status on their exceptions and/or deviations will be notified by the Authority and will be allowed to

retract the exception and/or deviation and continue in the evaluation process. Any exceptions and/or deviation that receive a “fail” status and the Offeror cannot or does not retract the requested change may result in the firm being eliminated from further evaluation.

4. Cost and Price Proposal

As part of the cost and price proposal, the Offeror shall submit proposed pricing to provide the services described in Exhibit A, Scope of Work.

The Offeror shall complete the "Price Summary Sheet" form included with this RFP (Exhibit B), and furnish any narrative required to explain the prices quoted in the schedules. It is anticipated the Agreement resulting from this solicitation, if awarded, will be a time-and-expense contract with fully-burdened firm-fixed per unit cost to complete the Scope of Work, included in the RFP as Exhibit A.

5. Appendices

Information considered by Offeror to be pertinent to this project and which has not been specifically solicited in any of the aforementioned sections may be placed in a separate appendix section. Offerors are cautioned, however, that this does not constitute an invitation to submit large amounts of extraneous materials. Appendices should be relevant and brief.

B. FORMS

1. Campaign Contribution Disclosure Form

In conformance with the statutory requirements of the State of California Government Code Section 84308, part of the Political Reform Act and Title 2, California Code of Regulations 18438 through 18438.8, regarding campaign contributions to members of appointed Board of Directors, Offeror is required to complete and sign the Campaign Contribution Disclosure Form provided in this RFP and submit as part of the proposal.

This form **must** be completed regardless of whether a campaign contribution has been made or not and regardless of the amount of the contribution.

The prime contractor, subconsultants, lobbyists and agents are required to report all campaign contributions made from the proposal submittal date up to and until the Board of Directors makes a selection.

Offeror is required to submit only **one** copy of the completed form(s) as part

of its proposal.

Offeror is required to report any campaign contributions made by the prime contractor, subconsultants, lobbyists and agents after the proposal submittal date, and up to the anticipated Board of Directors selection. The Offeror shall use the campaign contribution form for any additional reporting. The forms must be submitted at least fifteen (15) calendar days prior to the Board Committee date of June 12, 2024 and sent via e-mail to the Senior Contract Administrator.

2. Status of Past and Present Contracts Form

Offeror shall complete and sign the form entitled “Status of Past and Present Contracts” provided in this RFP and submit as part of its proposal. Offeror shall identify the status of past and present contracts where the firm has either provided services as a prime vendor or a subcontractor during the past five (5) years in which the contract has been the subject of or may be involved in litigation with the contracting authority. This includes, but is not limited to, claims, settlement agreements, arbitrations, administrative proceedings, and investigations arising out of the contract. Offeror shall have an ongoing obligation to update the Authority with any changes to the identified contracts and any new litigation, claims, settlement agreements, arbitrations, administrative proceedings, or investigations that arise subsequent to the submission of Offeror's proposal.

A separate form must be completed for each identified contract. Each form must be signed by the Offeror confirming that the information provided is true and accurate.

3. Proposal Exceptions and/or Deviations Form

Offerors shall complete the form entitled “Proposal Exceptions and/or Deviations” provided in this RFP and submit it as part of the original proposal. For each exception and/or deviation, a new form should be used, identifying the exception and/or deviation and the rationale for requesting the change. Exceptions and/or deviations submitted after the proposal submittal date will not be reviewed nor considered by the Authority.

SECTION III: EVALUATION AND AWARD

SECTION III. EVALUATION AND AWARD

A. EVALUATION CRITERIA

The Authority will evaluate the offers received based on the following criteria:

1. Qualifications of the Firm **20%**

Technical experience in performing work of a closely similar nature; strength and stability of the firm; strength, stability, experience and technical competence of subcontractors; assessment by client references.

2. Staffing and Project Organization **25%**

Qualifications of project staff, particularly key personnel and especially the Project Manager; key personnel's level of involvement in performing related work cited in "Qualifications of the Firm" section; logic of project organization; adequacy of labor commitment; concurrence in the restrictions on changes in key personnel.

3. Work Plan **35%**

Depth of Offeror's understanding of Authority's requirements and overall quality of work plan; logic, clarity and specificity of work plan; appropriateness of resource allocation; utility of suggested technical or procedural innovations.

4. Cost and Price **20%**

Reasonableness of the firm-fixed per unit cost; competitiveness with other offers received; adequacy of data in support of figures quoted.

B. EVALUATION PROCEDURE

An evaluation committee will be appointed to review all proposals received for this RFP. The committee is comprised of Authority staff and may include outside personnel. The committee members will evaluate the written proposals using criteria identified in Section III A. A list of top-ranked proposals, firms within a competitive range, will be developed based upon the totals of each committee members' score for each proposal.

During the evaluation period, the Authority may interview some or all of the proposing firms. The Authority has established March 14, 2024, as the date to conduct interviews. All prospective Offerors are asked to keep this date available. No other interview dates will be provided, therefore, if an Offeror is unable to attend the interview on this date, its proposal may be eliminated from further discussion. The interview may consist of a short presentation by the Offeror after which the

evaluation committee will ask questions related to the firm's proposal and qualifications.

At the conclusion of the proposal evaluations, the evaluation committee will score the proposals to develop a competitive range. Offerors remaining within the competitive range may be asked to submit a Best and Final Offer (BAFO). In the BAFO request, the firms may be asked to provide additional information, confirm or clarify issues and submit a final cost/price offer. A deadline for submission will be stipulated.

At the conclusion of the evaluation process, the evaluation committee will recommend to the Finance and Administration Committee, the Offeror with the highest final ranking or a short list of top ranked firms within the competitive range whose proposal(s) is most advantageous to the Authority. The Board Committee will review the evaluation committee's recommendation and forward its recommendation to the Board of Directors for final action.

C. AWARD

The Authority's Board of Directors will consider the selection of the firm(s) recommended by the Board Committee.

The Authority may also negotiate contract terms with the selected Offeror prior to award, and expressly reserves the right to negotiate with several Offerors simultaneously and, thereafter, to award a contract to the Offeror offering the most favorable terms to the Authority.

Offeror acknowledges that the Authority's Board of Directors reserves the right to award this contract in its sole and absolute discretion to any Offeror to this RFP regardless of the evaluation committee's recommendation or recommendation of a Board Committee.

The Authority reserves the right to award its total requirements to one Offeror or to apportion those requirements among several Offerors as the Authority may deem to be in its best interest. In addition, negotiations may or may not be conducted with Offerors; therefore, the proposal submitted should contain Offeror's most favorable terms and conditions, since the selection and award may be made without discussion with any Offeror.

The selected Offeror will be required to submit to the Authority's Accounting department a current IRS W-9 form prior to commencing work.

D. NOTIFICATION OF AWARD AND DEBRIEFING

Offerors who submit a proposal in response to this RFP shall be notified via CAMM NET of the contract award. Such notification shall be made within three (3) business days of the date the contract is awarded.

Offerors who were not awarded the contract may obtain a debriefing concerning the strengths and weaknesses of their proposal. Unsuccessful Offerors, who wish to be debriefed, must request the debriefing in writing or electronic mail and the Authority must receive it within three (3) business days of notification of the contract award.

EXHIBIT A: SCOPE OF WORK

SCOPE OF WORK

PART A: PHYSICAL EXAMINATIONS AND VACCINATIONS

I. GENERAL INFORMATION

The Orange County Transportation Authority (OCTA) requires the services of Board Certified medical professionals and medical clinic specializing in Occupational Medicine and Therapy (Clinic) to perform the following services primarily for safety-sensitive examinees but may include fit for duty exams for non-safety sensitive examinees, job applicants, or anyone OCTA refers to Clinic (Examinee):

- Physical Examinations, to include California Department of Motor Vehicle (DMV) commercial driver certifications and fit for duty exams
- Functional Capacity Testing
- Vaccinations, specifically Hepatitis B / Titer
- Audiometric Evaluations
- Respiratory Protection Medical Evaluations/Clearance

II. SERVICE REQUIREMENTS

A. PHYSICAL EXAMINATIONS

1. The physician performing physical examinations shall be certified on the National Registry of Certified Medical Examiners.

2. Physical examinations shall include functional capacity testing to ensure candidates meet the minimum physical requirements of the position, as specified in the job analysis. Functional capacity testing for Coach Operator candidates shall include the physician monitoring the candidate as the individual operates behind an OCTA-approved Bus Operator chair at the clinic site. If questions arise regarding physical standards of the classification of an Examinee, the physician shall contact OCTA's Human Resources Department. OCTA shall contact the examining physician or another available physician if issues or questions arise.

3. All services provided shall be conducted in a professional, confidential and respectful manner.

4. All services performed for OCTA shall require prior authorization, which is an OCTA Authorization form signed by an OCTA representative. The form shall be dated and time-stamped (upon arrival and departure of the Examinee or applicant). Clinic shall require that all Examinees provide a picture identification (ID), from which medical personnel shall reproduce a copy for their records.

a. If further tests appear necessary, Clinic shall contact OCTA's Human Resources Department by telephone for authorization.

5. Clinic shall be responsible for maintaining the privacy of the Examinee, and is to avoid any conduct or remarks that might be construed as accusatorial or otherwise offensive or inappropriate.

6. If sleep apnea is identified as a condition, and Clinic has the equipment to perform the prescribed sleep apnea test, Clinic shall provide such testing. If equipment is not available, Clinic shall recommend a local facility where the test can be performed at low cost with readily available appointment times.

7. Clinic shall comply with procedures and forms developed by OCTA, Department of Transportation (DOT), and DMV as amended. Clinic shall be required to produce copies of the following forms/certifications as requested by OCTA. The forms and procedures include, but are not limited to:
   - OCTA Authorization forms
   - Physical exam reports
   - Logs and record books
   - Average wait time reports.

8. The applicable forms shall be completed and signed by the examining physician. Medical records shall be treated confidentially.
   a. For DMV certifications, the examining physician shall complete all clinic forms and/or forms required for a California Commercial Driver's License. All examination reports shall be dated and time-stamped by Clinic. Clinic shall have processes in place to provide the most updated DMV forms to those receiving medical certification.

9. The decision to hire, retain, or terminate employment is a function of OCTA's management exclusively. Clinic shall not provide OCTA's Examinees and applicants with any information related to employment, retention, or termination. If additional information regarding the physical qualifications of an Examinee is needed, OCTA will contact the examining physician.

10. Notification of results for physical examinations shall be provided to OCTA as soon as practicable
    a. For physical exams resulting in medical holds, Clinic shall verbally report to OCTA, immediately upon verification of medical hold by the physician. Following the verbal verification of a medical hold, Clinic shall send an email confirmation to the designated OCTA representative, including any applicable written report, excluding protected health information.

b. For physical exams not resulting in medical hold, notification shall be sent by Clinic to OCTA upon verification by the physician. In addition, written reports shall be made available to OCTA within twenty-four (24) hours or next business day of verification by the physician, excluding protected health information.
    1) OCTA shall access test results, forms, and physical exam reports via an employer portal.

11. At a minimum, Clinic shall be open to schedule and perform examinations requested by OCTA as follows:
    - Monday through Friday: 8:00 a.m. to 6:00 p.m.
    - Weekends: Saturdays and "on-call" the remainder of the weekend
    - A clinic that also offers a mobile health clinic to perform pre-employment DMV physical exams shall be preferred.

12. Clinic shall identify and communicate to OCTA qualified physicians who shall act as a backup when the primary physician is unavailable.

13. Clinic facility shall be located within approximately twenty-five (25) minutes for an individual to arrive from each of the following base locations:
    - Garden Grove Base:11800 Woodbury Rd, Garden Grove, CA. 92863
    - Santa Ana Base: 4301 W. MacArthur Blvd, Santa Ana, CA. 92704

14. Clinic shall submit an invoice to OCTA Human Resources by the 15th of every month for services rendered the prior month. The invoice, at minimum, shall include each service rendered the prior month, listing date of service, description, Examinee name, and OCTA Examinee ID number. The invoice shall also include a certification statement, signed by Clinic, that certifies the invoice to be true, complete, and a correct statement of reimbursable costs. The backup information included with the invoice is true, complete, and correct in all material respects.
    1) OCTA shall access invoices via an employer portal.

15. At its discretion, OCTA may conduct or hire an independent auditor to conduct an annual audit of Clinic and/or the laboratory to ensure compliance with OCTA policy, as well as DOT/Federal Transit Administration (FTA) guidelines, as amended.

16. OCTA will monitor the overall level of service provided by Clinic to ensure that all OCTA requirements are being met. OCTA will monitor Examinee wait times at Clinic, customer service complaints, response times, and errors made.

B. VACCINATIONS

1. Bloodborne Pathogens Hepatitis B:
    a. Clinic shall schedule and perform Hepatitis B vaccinations for all designated OCTA Examinees including service workers, facility technicians, field operations supervisors.
    b. Pre-exposure vaccinations shall be scheduled and given at day zero (0), thirty (30) days, and the final injection being in six (6)-months. It is understood that each Examinee electing to have the vaccinations shall be educated on the Bloodborne Pathogens Standard. Only Examinees who are listed as approved by OCTA are eligible for vaccinations.
    c. Exposure incidents occurring while on the job shall be treated as an industrial case. Upon initial examination, OCTA will provide physician with the following:
        - A copy of the Bloodborne Pathogens Standard
        - A description of the exposure incident
        - The exposed Examinee's relevant medical records
        - Any other pertinent information.
    d. OCTA's Safety Department shall receive initial and follow-up written reports containing the following:
        - Whether Hepatitis B vaccine was indicated for Examinee
        - Whether Examinee received the vaccination
        - Confirmation that Examinee is informed of the results of the evaluation
        - Confirmation that Examinee has been told of any medical conditions resulting from the exposure incident which would require further evaluation or treatment.
    e. All other findings or diagnosis shall remain confidential and not be included in the written report.

2. Post-Vaccination Testing for Hepatitis B Antibodies (Titer)
    a. Clinic shall perform post vaccination serological testing for those OCTA Examinees who have received the Hepatitis B vaccination series and are part of OCTA's Bloodborne Pathogens Program. Clinic shall provide OCTA's Safety Department a copy of the laboratory results within two (2) weeks.
    b. Those Examinees whose antibody tests show that they have not responded to the primary vaccination series shall be offered a second three (3)-dose vaccination series as defined in the Bloodborne Pathogens Hepatitis B above.
    c. Hepatitis B Titer testing shall be performed, when necessary, for existing Examinees in the Bloodborne pathogen program, or new Examinees entering into the program, who may have had the vaccination series in the past as identified by OCTA.

LIMITATION ON GOVERNMENTAL DECISIONS

Nothing contained in this Scope of Work permits Clinic's personnel to authorize or direct any actions, votes, appoint any person, obligate, or commit OCTA to any course of action or enter into any contractual agreement on behalf of OCTA. In addition, Clinic's personnel shall not provide information, an opinion, or a recommendation for the purpose of affecting a decision without significant intervening substantive review by OCTA personnel, counsel, and management.

END: SCOPE OF WORK, PART A: PHYSICAL EXAMINATIONS AND VACCINATIONS

SCOPE OF WORK

PART B: DRUG AND ALCOHOL TESTING SERVICES

GENERAL INFORMATION

OCTA employs approximately 800 safety-sensitive workers and requires a "full-service" drug and alcohol testing provider (Clinic), operating at a fixed location within Orange County.

This full-service includes providing all necessary staff, facilities, a collection site, a laboratory, specimen transportation, forms, supplies, and equipment to collect, test, verify, and report results in compliance with the DOT, FTA regulations, and with the applicable provisions OCTA's Drug and Alcohol Policy Manual, including non-federal testing, as these regulations and policies are in effect now and as they may change at any time during the term of this contract..

Clinic shall be capable of continuously meeting this Scope of Work including the performance standards specified herein.

This Scope of Work is distinct and independent from any other scopes of work outlined in the agreement.

DRUG AND ALCOHOL TESTING REQUIREMENTS

Clinic shall provide split sample urine and oral fluid drug testing and alcohol breath testing for the following:

- DOT/FTA: Pre-Employment, Random, Post Accident, Reasonable Suspicion, Follow Up, and Return to Duty testing using federal drug testing custody and control forms and DOT Alcohol Testing Forms. An electronic version of the Federal Drug Testing Custody and Control Form (eCCF) is required.

- NON-DOT (OCTA): Behavioral Contract, Probable Cause, Post Accident, and Biennial testing using non-federal drug testing custody and control forms and non-federal Alcohol Testing Forms. All non-DOT testing shall mirror DOT/FTA testing procedures unless otherwise stated.

Clinic shall comply with the following as they are in effect now and as they may change at any time during the term of this contract:

1. 49 CFR PART 40, PROCEDURES FOR TRANSPORTATION WORKPLACE DRUG AND ALCOHOL TESTING PROGRAMS.

2. 49 CFR PART 655, PREVENTION OF ALCOHOL MISUSE AND PROHIBITED DRUG USE IN TRANSIT OPERATIONS.

3. The applicable provisions of OCTA's Drug and Alcohol Policy Manual.

4. Industry best-practices and standards.

5. All other local, state, and federal laws, regulations, and ordinances applicable to the services provided.

6. The Performance Standards specified in this Scope of Work.

7. Any subsequent and reasonable OCTA issued guidance and procedures.

GENERAL SERVICE REQUIREMENTS

Clinic shall provide full-service drug and alcohol testing to walk-ins, without delay, without prior arrangement, nor appointment, twenty-four (24)-hours per day, seven (7)-days per week, 365 days per year, at an established collection site, located within central Orange County. The collection site shall be safe, clearly marked, easily accessible, and provide ample free parking. All collection site signage, documentation, forms, and communications shall reflect the same business name as shown in the contract.

Clinic shall provide a single point of contact to act as the primary liaison between Clinic and OCTA for daily operations, coordination, and the timely resolution of any operational challenges or inquiries.

Prior to conducting a drug and alcohol test, Clinic shall obtain an OCTA written authorization form, signed by an OCTA representative, and shall perform the test(s) specified on the form. Verbal authorization from OCTA may be accepted in exceptional circumstances. Clinic shall stamp each authorization form with the date and time of the Examinee's arrival and departure from the collection site.

Unless previously approved by OCTA, Clinic shall not require Examinees to complete any consent forms or paperwork other than drug testing custody and control forms (CCF) and alcohol testing forms (ATF).

Drug and alcohol testing wait times shall be kept to a minimum. Clinic shall perform all services in a professional and confidential manner, process all test paperwork without delay, and timely report results, anomalies, and concerns to OCTA.

Clinic shall immediately notify OCTA of positive test results or test anomalies in the method prescribed by OCTA.

Clinic shall post all completed forms, including testing documents, and results to a web-based application that has been reviewed and approved by OCTA. The web-based application shall always be accessible to OCTA during the term of this agreement.

By the 15th of each month, and in a format specified by OCTA, Clinic shall email an itemized invoice and physically deliver all original test forms, results, affidavit of corrections, and associated documents to OCTA, for all tests conducted in the preceding month.

Clinic shall grant OCTA permission to enter, inspect, observe, and interview Clinic's staff, facilities, records, certifications, procedures, and equipment at any time. Upon request, Clinic shall also perform simulated drug and alcohol testing under observation.

During the term of this agreement, OCTA may provide Clinic with supplementary, judicious guidance and procedures when deemed necessary to enhance operational efficiency and streamline the workflow associated with this Scope of Work.

PERFORMANCE STANDARDS

The services outlined in this Scope of Work are mission critical, directly impact public safety, and are subject to federal oversight. OCTA requires unwavering accuracy and strict adherence to all applicable regulations, protocols, procedures, and Performance Standards.

The Performance Standards (Attachment D) articulate the precise expectations and requirements for each instance of service provided under this agreement. Clinic shall be obligated to exert every reasonable effort to ensure that the service provided meets or exceeds the Performance Standards.

If Clinic fails to meet the Performance Standards, OCTA may, at its discretion, request that Clinic forfeit payment for that instance of service or pay a penalty as prescribed. The forfeited payment shall be equal to the compensation that would have been due for that specific service, or as specified in the Performance Standards.

OCTA retains the discretion to withhold the forfeited payment or penalty from any outstanding payments owed to Clinic or deduct the forfeited amount from any future payments owed to Clinic.

In the event of a dispute regarding Clinic's compliance with the Performance Standards, both parties shall engage in good faith efforts to resolve the dispute promptly and amicably.

CONTINUITY OF SERVICE PLAN REQUIREMENT

At the time of proposal, Clinic shall provide OCTA with a comprehensive written plan detailing strategies for ensuring uninterrupted service delivery in the face of potential disruptions. These disruptions should encompass a range of scenarios, including but not limited to the temporary or permanent loss of access to the collection facility, equipment malfunctions, staffing challenges, or any other foreseeable events that could impede the fulfillment of services as outlined in this document.

The Continuity of Service Plan is expected to encompass a thorough assessment of potential risks and challenges, a set of specific strategies, protocols, and contingency plans tailored to address each identified risk, a well-defined implementation timeline, clear assignment of responsibilities to key personnel, efficient communication procedures to promptly inform OCTA of disruptions, documentation of contractual or external partnerships that may be activated during disruptions, and a framework for ongoing monitoring, evaluation, and refinement of the Continuity of Service Plan.

Upon submission, OCTA will review the plan, and if necessary, request revisions or clarifications before approval. Once approved, Clinic shall promptly put the plan into action and maintain it throughout the duration of this agreement. Additionally, Clinic shall be required to promptly notify OCTA of any disruptions or events that trigger the activation of the Continuity of Service Plan. This Continuity of Service Plan Requirement serves as a critical assurance of Clinic's preparedness to address potential challenges while upholding the high standard of service expected by OCTA.

ADOPTIONS AND ATTACHMENTS

The following are hereby adopted as part of this Scope of Work, as they are in effect now and as they may change at any time during the term of this contract.

1. 49 CFR PART 40, PROCEDURES FOR TRANSPORTATION WORKPLACE DRUG AND ALCOHOL TESTING PROGRAMS (Attachment A)

2. 49 CFR PART 655, PREVENTION OF ALCOHOL MISUSE AND PROHIBITED DRUG USE IN TRANSIT OPERATIONS (Attachment B)

3. OCTA’s Drug and Alcohol Policy Manual (Attachment C)

4. Performance Standards (Attachment D)

LIMITATION ON GOVERNMENTAL DECISIONS

Nothing contained in this Scope of Work permits Clinic’s personnel to authorize or direct any actions, votes, appoint any person, obligate, or commit OCTA to any course of

action or enter into any contractual agreement on behalf of OCTA. In addition, Clinic's personnel shall not provide information, an opinion, or a recommendation for the purpose of affecting a decision without significant intervening substantive review by OCTA personnel, counsel, and management.

END: SCOPE OF WORK, PART B: DRUG AND ALCOHOL TESTING SERVICES

Title 49 —Transportation
Subtitle A —Office of the Secretary of Transportation

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

Authority: 49 U.S.C. 102, 301, 322, 5331, 20140, 31306, and 54101 *et seq.*

Source: 65 FR 79526, Dec. 19, 2000, unless otherwise noted.

Editorial Note: Nomenclature changes to part 40 appear at 73 FR 33329, June 12, 2008.

Subpart A—Administrative Provisions

§ 40.1 Who does this regulation cover?

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

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

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

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

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

Adulterated specimen. A specimen that has been altered, as evidenced by test results showing either a substance that is not a normal constituent for that type of specimen or showing an abnormal concentration of an endogenous substance.

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

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

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

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

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

Alcohol screening device (ASD). A breath or saliva device, other than an EBT, that is approved by the National Highway Traffic Safety Administration (NHTSA) and appears on ODAPC's Web page for “Approved Screening Devices to Measure Alcohol in Bodily Fluids” because it conforms to the model specifications from NHTSA.

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.

Alternate specimen. An authorized specimen, other than the type of specimen previously collected or attempted to be collected.

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

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

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

Collection container. A container used to collect a specimen.

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

Commercial Driver's License Drug and Alcohol Clearinghouse (Clearinghouse). A database, administered by the Federal Motor Carrier Safety Administration, containing records of commercial motor vehicle drivers' violations of controlled substances and alcohol testing program requirements, as set forth in part 382 of this title, as well as their return-to-duty status.

Confirmatory drug test. A second analytical procedure performed on a different aliquot of the original specimen to identify and quantify a specific drug or drug metabolite.

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

Cutoff. The analytical value (*e.g.,* drug or drug metabolite concentration) used as the decision point to determine a result (*e.g.,* negative, positive, adulterated, invalid, or substituted) or the need for further testing.

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 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). For purposes of this part, the United States Coast Guard

(USCG), in the Department of Homeland Security, is considered to be a DOT agency for drug testing purposes only since the USCG regulation does not incorporate Part 40 for its alcohol testing program. 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 opioids.

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 that is approved by the National Highway Traffic Safety Administration (NHTSA) for the evidential testing of breath at the .02 and .04 alcohol concentrations, and appears on ODAPC's Web page for "Approved Evidential Breath Measurement Devices" because it conforms with the model specifications available from NHTSA.

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

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

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

Invalid result. The result reported by an HHS-certified in accordance with the criteria established by HHS when a positive, negative, adulterated, or substituted result cannot be established for a specific drug or specimen validity test.

Laboratory. Any U.S. laboratory certified by HHS under the National Laboratory Certification Program as meeting the minimum standards set by HHS; or, in the case of foreign laboratories, a laboratory approved for participation by DOT under this part.

Limit of Detection (LOD). The lowest concentration at which the analyte (*e.g.,* drug or drug metabolite) can be identified.

Limit of Quantitation (LOQ). For quantitative assays, the lowest concentration at which the identity and concentration of the analyte (*e.g.,* drug or drug metabolite) can be accurately established.

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

Negative result. The result reported by an HHS-certified laboratory to an MRO when a specimen contains no drug or the concentration of the drug is less than the cutoff concentration for the drug or drug class and the specimen is a valid specimen.

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

Oral fluid specimen. A specimen that is collected from an employee's oral cavity and is a combination of physiological fluids produced primarily by the salivary glands. An oral fluid specimen is considered to be a direct observation collection for all purposes 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 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 specimen validity testing. The primary specimen is the portion of the donor's subdivided specimen designated as the primary ("A") specimen by the collector to distinguish it from the split ("B") specimen, as defined in this section.

Positive result. The result reported by an HHS-certified laboratory when a specimen contains a drug or drug metabolite equal to or greater than the cutoff concentrations.

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

Reconfirmed. The result reported for a split (Bottle B) specimen when the second HHS-certified laboratory corroborates the original result reported for the primary (Bottle A) specimen.

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

Rejected for testing. The result reported by an HHS-certified laboratory when no tests are performed for a specimen because of a fatal flaw or a correctable flaw that is not corrected.

Screening 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 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 DOT qualifications, if applicable. Service agents are not employers for purposes of this part.

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

Specimen. Fluid, breath, or other material collected from an employee at the collection site for the purpose of a drug or alcohol test.

Specimen bottle. The bottle that, after being sealed and labeled according to the procedures in this part, is used to hold a primary ("A") or split ("B") specimen during transportation to the laboratory. In the context of oral fluid testing, it may be referred to as a "vial," "tube," or "bottle."

Split specimen. In drug testing, the specimen that is sent to a first laboratory and stored with its original seal intact, and which is transported to a second laboratory for retesting at the employee's request following MRO verification of the primary specimen as positive, adulterated or substituted.

Split specimen collection. A collection in which the single specimen collected is divided into two separate specimen bottles, the primary specimen (Bottle A) and the split specimen (Bottle B).

SSN or Employee ID No. This number serves as a unique identifier that must be used on the Federal Drug Testing Custody and Control Form (CCF) or Alcohol Testing Form (ATF) for a donor, on the MRO's reports, on SAP reports, or on other documents that are required under this part. For all purposes of this part, this term means: only the Commercial Driver's License (CDL) Number and State of issuance for drivers tested under the authority of the Federal Motor Carrier Safety Administration (FMCSA); and, for all drivers and other safety-sensitive employees tested under the authority of the other DOT agencies, this can be the individual's actual Social Security Number, a unique identifier issued by the employer, a State-issued identification card number, a State-issued driver's license number (including a CDL number) or any other State-issued or federally-issued identification number.

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. An employee's specimen not consistent with a normal human specimen, as determined by HHS (*e.g.,* 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).

Undiluted (neat) oral fluid. An oral fluid specimen to which no other solid or liquid has been added. For example: A collection device that uses a diluent (or other component, process, or method that modifies the volume of the testable specimen) must collect at least 1 mL of undiluted (neat) oral fluid.

Urine specimen. Urine collected from an employee at the collection site for the purpose of a drug test.

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, Aug. 23, 2006; 71 FR 55347, Sept. 22, 2006; 73 FR 35969, June 25, 2008; 75 FR 49861, Aug. 16, 2010; 76 FR 59577, Sept. 27, 2011; 80 FR 19553, Apr. 13, 2015; 81 FR 52365, Aug. 8, 2016; 82 FR 52243, Nov. 13, 2017; 88 FR 27636, May 2, 2023]

§ 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.

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. When conducting a urine DOT drug test, you must discard any excess urine left over from a DOT test and collect a separate urine 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 specimens other than those tests specifically authorized by this part or DOT agency regulations. For example, you must not test a DOT specimen for additional drugs. In addition, a laboratory is prohibited from making a DOT specimen available for a DNA test or other types of specimen identity testing.

(d) When a DOT urine drug test collection is conducted as part of a physical examination required by DOT agency regulations, it is permissible to conduct medical tests related to this physical examination (*e.g.,* for glucose) on any specimen remaining in the collection container after the DOT portion has been sealed into the specimen bottles.

(e) A non-DOT drug or alcohol test administered, as part of a physical examination, is not a DOT drug or alcohol test for purposes of this part and/or related DOT agency drug and alcohol testing rules, if that test was performed to determine if an employee is medically qualified for a license or certificate. Consequently, the results of such a test do not have consequences under this part.

(f) 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.

(g) 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.

(h) No one is permitted to conduct a DOT drug or alcohol test on an individual who is not a DOT-regulated employee, as defined by the DOT agency regulations.

[65 FR 79526, Dec. 19, 2000, as amended at 88 FR 27637, May 2, 2023]

§ 40.14 What collection information must employers provide to collectors?

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

(a) Full name of the employee being tested.

(b) SSN or Employee ID No.

(c) Laboratory name and address (can be pre-printed on the CCF).

(d) Employer name, address, phone number, and fax number (can be pre-printed on the CCF at Step 1–A).

(e) DER information required at § 40.35 of this part.

(f) MRO name, address, phone number, and fax number (can be pre-printed on the CCF at Step 1–B).

(g) The DOT Agency which regulates the employee's safety-sensitive duties (the checkmark can pre-printed in the appropriate box on the CCF at Step 1–D).

(h) Test reason, as appropriate: Pre-employment; Random; Reasonable Suspicion/Reasonable Cause; Post-Accident; Return-to-Duty; and Follow-up.

(i) Whether the test is to be observed or not (see § 40.67 of this part).

(j) (Optional) C/TPA name, address, phone, and fax number (can be pre-printed on the CCF).

(k) Specimen type to be collected (*i.e.,* oral fluid or urine).

[75 FR 59107, Sept. 27, 2010, as amended at 88 FR 27637, May 2, 2023]

§ 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;

(C) For a verified negative result, the employee will not be required to submit an alternate specimen for the same testing action. For a cancelled result, the employee could be required to submit an alternate specimen on a re-collection; and

(D) 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.

[65 FR 79526, Dec. 19, 2000, as amended at 88 FR 27637, May 2, 2023]

§ 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 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 (either an oral fluid specimen or a urine specimen under direct observation).

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

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

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

(5) You must ensure that the collector conducts the collection under direct observation (either an oral fluid specimen or a urine specimen 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; 75 FR 59107, Sept. 27, 2010; 88 FR 27637, May 2, 2023]

§ 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)

(1) Yes, as an employer, you must, after obtaining an employee's written consent, request the information about the employee listed in paragraphs (b) through (j) 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 transferring 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.

(2) If you are an employer regulated by FMCSA, you must comply with the requirements of this section by using the FMCSA's Drug and Alcohol Clearinghouse in accordance with 49 CFR 382.71(a). In addition, you must continue to comply with the requirements of this § 40.25 when checking an employee's testing history with employers regulated by a DOT operating administration other than FMCSA.

(3) If you are an employer regulated by FMCSA, with a prospective employee subject to drug and alcohol testing with a DOT agency other than FMCSA, you must continue to request the information about the employee listed in paragraphs (b) through (j) of this section. For example, if you are an employer

regulated by both FMCSA and PHMSA, and you are hiring an employee to perform functions regulated by both DOT agencies, then you must query FMCSA's Clearinghouse to satisfy FMCSA's requirements and you must request the information listed in paragraphs (b) through (j) of this section to satisfy PHMSA's requirements.

(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).

[65 FR 79526, Dec. 19, 2000, as amended at 88 FR 27637, May 2, 2023]

§ 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 U.S. Department of Transportation Drug and Alcohol Testing MIS Data Collection Form to report that data. You must use the form and instructions referenced at appendix J 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.

[84 FR 16773, Apr. 23, 2019, as amended at 88 FR 27638, May 2, 2023]

§ 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]

Subpart C—Urine Collection Personnel

§ 40.31 Who may collect 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 urine collector must meet training requirements of § 40.33.

(c) An oral fluid collector must meet the training requirements of § 40.35.

(d) To avoid the appearance of a conflict of interest, if you are the immediate supervisor of the employee being tested, you must 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.

(e) 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.

(f) Employees are not permitted to be their own collector.

(1) An employee who is a qualified collector is not permitted to be their own collector; another qualified collector must perform the collection in accordance with this part.

(2) To avoid a potential conflict of interest, a collector must not be related to the employee being tested (*e.g.,* spouse, ex-spouse, relative) or a close personal friend.

[65 FR 79526, Dec. 19, 2000, as amended at 88 FR 27637, May 2, 2023]

§ 40.33 What training requirements must a collector meet for urine collection?

To be permitted to act as a urine 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. DOT agency regulations, the DOT Urine Specimen Collection Procedures Guidelines, and other materials are available from ODAPC (Department of Transportation, 1200 New Jersey Avenue SE., Washington DC, 20590, 202–366–3784, or on the ODAPC Web site (*https://www.transportation.gov/odapc*). You must keep current on any changes to these materials. You must subscribe to the ODAPC list-serve at: *https://www.transportation.gov/odapc/get-odapc-email-updates*.

(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) 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. Errors that cause cancellation but occur outside the collection process (*e.g.,* when a specimen is crushed or otherwise damaged during the transportation process, or is lost in transit), the cancellation would not be the result of an error by the collector during the collection process and does not require the collector to be retrained.

(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; 82 FR 52244, Nov. 13, 2017; 88 FR 27638, May 2, 2023]

§ 40.35 What training requirements must a collector meet for oral fluid collection?

To be permitted to act as an oral fluid 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 Oral Fluid Specimen Collection Procedures Guidelines," and DOT agency regulations applicable to the employers for whom you perform collections. DOT agency regulations, guidelines, and other materials are available from ODAPC (Department of Transportation, 1200 New Jersey Avenue SE, Washington DC, 20590, 202–366–3784, or on the ODAPC website (*https://www.transportation.gov/odapc*). You must keep current on any changes to these materials. You must subscribe to the ODAPC list-serve at: *https://www.transportation.gov/odapc/get-odapc-email-updates*.

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

(1) Training on the testing procedures of this part;

(2) Training to proficiency in the operation of the particular oral fluid collection device(s) you will be using.

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

(4) "Problem" collections (*e.g.,* situations like "dry mouth" and attempts to tamper with a specimen);

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

(6) 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 for each device you will use.

(1) The five mock collections for each device must include one uneventful collection scenario, one insufficient specimen quantity scenario; one scenario in which the employee has something in their mouth that might interfere with the collection; one scenario in which the employee attempts to tamper with the specimen; and one scenario in which the employee refuses to sign the CCF. For each of the five mock collections, the collector must check the expiration date of the device, show it to the employee, and record the date on the CCF used. The collector must ensure, when applying the labels, they do not cover the expiration dates.

(2) Another person must monitor and evaluate your performance, in person or by a means that provides real-time observation and interaction between you and the qualified collector, who must 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 one year;

(ii) Conducting collector training under this part for at least one year; or

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

(d) ***Schedule for qualification training and initial proficiency demonstration.*** 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).

(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.

[88 FR 27638, May 2, 2023]

§ 40.36 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.

[65 FR 79526, Dec. 19, 2000. Redesignated at 88 FR 27639, May 2, 2023]

Subpart D—Collection Sites, Forms, Equipment and Supplies Used in DOT Urine and Oral Fluid Collections

§ 40.40 What form is used to document a DOT collection?

(a) The Federal Drug Testing Custody and Control Form (CCF) must be used to document every collection required by the DOT drug testing program. You may view this form on the Department's website (*https://www.transportation.gov/odapc*) or the HHS website (*https://www.workplace.samhsa.gov*).

(b) You must not use a non-Federal form or an expired CCF to conduct a DOT 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 CCF to these participants. You must also affirmatively notify these participants that they must not use an expired CCF.

(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 any other appropriate contact information (*e.g.,* an email address of the employer and the MRO), including the DER's name and contact information. All of this information must be preprinted, typed, or handwritten. Fax numbers may be included but are not required. The MRO information must include the physician's name and address, as opposed to only a generic clinic, health care organization, company name, or post office box. This information is required, and an employer, collector, service agent or any other party is prohibited from omitting it. In addition, a C/TPA's name, address, telephone and fax numbers, and any other appropriate contact information should 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 and fax numbers, and any other appropriate contact information.

(3) As an employer you may preprint the box in Step 1–D of the CCF for the DOT agency under whose authority the test will occur.

(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. If a collection takes place at a clinic, the actual address of the clinic should be used, not a corporate address of the collection company. If the collection takes place onsite at the employer, the employer's address must be noted as the collection site address. If the collection takes place in a "mobile unit" or at an accident site, the collector must enter the actual location address of the collection or as near an approximation as possible. The collector must ensure that the required collector telephone number is the number that the laboratory, MRO, or employer may use to directly contact the individual collector and/or the collector's supervisor during the collection site's business hours. The collector must not provide a number for a call center.

(5) When using an electronic CCF, 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 form.

(d) Under no circumstances may the CCF transmit personal identifying information about an employee (other than a SSN or Employee ID No.) 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.

(f) An employer who uses an electronic CCF must ensure that the collection site, the primary and split laboratories, and MRO have compatible systems, and that the employee and any other program participants in the testing process will receive a legible copy of the CCF.

[65 FR 79526, Dec. 19, 2000, as amended at 66 FR 41950, Aug. 9, 2001; 75 FR 59107, Sept. 27, 2010; 76 FR 59577, Sept. 27, 2011; 80 FR 19553, Apr. 13, 2015; 82 FR 52244, Nov. 13, 2017. Redesignated and amended at 88 FR 27639, May 2, 2023]

§ 40.41 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 collections. You are also prohibited from using non-Federal forms for DOT 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. Redesignated and amended at 88 FR 27639, June 1, 2023]

§ 40.42 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.

[65 FR 79526, Dec. 19, 2000. Redesignated at 88 FR 27639, May 2, 2023]

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

§ 40.44 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.

[65 FR 79526, Dec. 19, 2000. Redesignated at 88 FR 27639, May 2, 2023]

§ 40.45 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.

[65 FR 79526, Dec. 19, 2000. Redesignated at 88 FR 27639, May 2, 2023]

§ 40.47 Where does an oral fluid collection for a DOT drug test take place?

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

(b) If you are operating an oral fluid collection site:

(1) You must ensure that it meets the security requirements of § 40.48;

(2) The site may be a permanent or temporary facility located either at the work site or at a remote site;

(3) The 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; and

(4) You must have all necessary personnel, materials, equipment, and facilities that include privacy and supervision to provide for the collection, temporary storage, and shipping of specimens to a laboratory, and a suitable clean surface for writing.

(c) If a collection site is not accessible and there is an immediate requirement to collect an oral fluid specimen (*e.g.,* an accident investigation), another site may be used for the collection, if the collection is performed by a collector who has been trained to collect oral fluid specimens in accordance with this part and the manufacturer's procedures for the collection device.

[88 FR 27640, May 2, 2023]

§ 40.48 What steps must operators of collection sites and collectors take to protect the security and integrity of oral fluid 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) Ensure that access to collection materials and specimens is effectively restricted;

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

(3) Ensure the security of the facility during the collection process to maintain privacy to the employee and prevent distraction of the collector. Limited-access signs must be posted.

(c) 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 "dry mouth" situation (*see* § 40.72(b)(1)), you may conduct a collection for another employee as long as the employee with "dry mouth" remains supervised.

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

(3) Ensure you are the only person in addition to the employee who handles the specimen before it is 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.

(d) 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 oral fluid 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 (d).

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

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

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

[88 FR 27640, May 2, 2023]

§ 40.49 What materials are used to collect oral fluid specimens?

For each DOT drug test, you must use a collection device meeting the requirements of appendix B of this part.

[88 FR 27640, May 2, 2023]

§ 40.51 What materials are used to send oral fluid 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 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.

[88 FR 27640, May 2, 2023]

Subpart E—Specimen Collections

§ 40.61 What are the preliminary steps in the drug testing 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, the DER must determine whether the employee has refused to test (*see* §§ 40.191(a)(1) and 40.355(i)). In a situation where a C/TPA has notified an owner/operator or other individual employee to report for testing (other than for a pre-employment test) and the employee does not appear, the C/TPA must determine whether the employee has refused to test (*see* §§ 40.191(a)(1) and 40.355(j)).

(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 ensure, to the greatest extent practicable, that the alcohol test is completed before the drug testing 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 a specimen from an unconscious employee to conduct a drug test under this part.

(4) You must not catheterize a conscious employee for purposes of a urine test. However, you must inform an employee who normally voids through self-catheterization that the employee is required to provide a specimen in that manner. If an employee normally voids through self-catheterization, but declines to do so for the urine test, the collector should notify the DER of the circumstances, so that the actual employer can determine whether the situation constitutes a refusal to test by the employee.

(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, and notify the employee that instructions for completing the CCF can be found at the HHS (*https://www.samhsa.gov/workplace*) and DOT (*https://www.transportation.gov/odapc*) websites.

(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, either conduct a directly observed urine collection using direct observation procedures (*see* § 40.67) or an oral fluid specimen collection, make a note on the CCF and continue with collection process; 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.)

[65 FR 79526, Dec. 19, 2000, as amended at 88 FR 27640, May 2, 2023]

§ 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) Ensure all items under Step 1 of the CCF are complete and accurate (*e.g.,* if Step 1.D is not checked, put a check mark for the "Specify DOT Agency" under the authority of which the test will take place; if the address where the collection is actually taking place is not in Step 1.G, update that.)

(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 complete Step 2 by noting the conduct in the "Remarks" line of the CCF and the fact that the collection

was observed by checking the "Observed" box. 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.

[65 FR 79526, Dec. 19, 2000, as amended at 75 FR 59107, Sept. 27, 2010; 88 FR 27641, May 2, 2023]

§ 40.65 What does the collector check for when the employee presents a urine 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 urine collection using direct observation procedures (*see* § 40.67) or an oral fluid collection.

(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 (including oral fluid) and send the two sets of specimens to their respective laboratories. This is true even in a case in which the original specimen has insufficient volume and 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, or smell of bleach), you must immediately conduct a new urine collection using direct observation procedures (*see* § 40.67) or an oral fluid collection.

(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; 88 FR 27641, May 2, 2023]

§ 40.67 When and how is a directly observed urine 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)).

(4) You realize a collection under direct observation was required but was not conducted or the service agent informs you that a direct observation should have been collected but was not (*see* paragraph (n) of this section).

(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 paragraph (a) 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));

(4) The original specimen appeared to have been tampered with (*see* § 40.65(c)(1)); or

(5) The test reason is return-to-duty or follow-up.

(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.

(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 paragraphs (c)(2) through (4) of this section) 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.

(1) You must never permit an opposite gender person to act as the observer.

(2) The observer can be a different person from the collector and need not be a qualified collector.

(3) If a same gender collector cannot be found or in circumstances of nonbinary or transgender employees:

(i) If the employer has a standing order to allow oral fluid testing in such situations, the collector will follow that order;

(ii) If there is no standing order from the employer, the collector must contact the DER and either conduct an oral fluid test if the collection site is able to do so, or send the employee to a collection site acceptable to the employer for the oral fluid test.

(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 a service agent, 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 50223, Aug. 26, 2008; 73 FR 62910, Oct. 22, 2008; 73 FR 70284, Nov. 20, 2008; 74 FR 37952, July 30, 2009; 82 FR 52244, Nov. 13, 2017; 88 FR 27641, May 2, 2023]

§ 40.69 How is a monitored urine collection conducted?

(a) As stated in § 40.42(f)(2), if you are conducting a urine collection in a multi-stall restroom and you cannot secure all sources of water and other substances that could be used for adulteration and substitution, you must conduct a monitored collection. This is the only circumstance in which you must conduct a monitored collection.

(b) 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.

(c) 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.

(d) 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.

(e) 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(c)(2)(3)).

(f) 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.

(g) 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).

(h) 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; 88 FR 27641, May 2, 2023]

§ 40.71 How does the collector prepare the urine specimen?

(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) After the collection, check the box on the CCF (Step 2) indicating that this was a “Urine” and “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; 88 FR 27641, May 2, 2023]

§ 40.72 What steps does the collector take in the collection process before the employee provides an oral fluid specimen?

(a) The collector requests that the employee open the employee's mouth, and the collector inspects the oral cavity to ensure that it is free of any items that could impede or interfere with the collection of an oral fluid specimen (*e.g.,* candy, gum, food, or tobacco) or could be used to adulterate, substitute, or alter the specimen.

(1) If the collector finds indication(s) of anything identified above, the collector will ask the employee to lift their tongue and/or separate their cheek from their gum to permit full inspection. If this occurs, the employee may cleanse his or her hands, but must not decline the collector's request for further inspection.

(2) If the employee claims that he or she has a medical condition that prevents opening his or her mouth for inspection, the collector follows the procedure described in § 40.193(a).

(3) If the collector observes materials brought to the collection site or the employee's conduct clearly indicates an attempt to adulterate, substitute, or alter the specimen, the collector must terminate the collection, note the circumstances in the Remarks section of the CCF, and report the circumstances to the DER, so that the employer can decide whether to deem the situation a refusal in accordance with § 40.191(a).

(b) If an item is present that might impede or interfere with the collection of an oral fluid specimen, the collector must request the employee remove the item.

(1) If the employee removes any item that could impede or interfere with the collection of an oral fluid specimen, the employee has abnormally colored saliva, or the employee claims to have "dry mouth," then the collector must give the employee water, up to 8 ounces, to rinse their mouth. The employee may drink the water. The collector must then wait 10 minutes before beginning the specimen collection.

(2) If the employee refuses to remove the item or rinse, the collector must terminate the collection, note the circumstances in the Remarks section of the CCF, and report the information to the DER to test as described in § 40.191(a)(8) (failure to cooperate), so that the employer can decide whether to deem the situation a refusal.

(c) If there is nothing of concern in the oral cavity and no "dry mouth" condition, the collector starts a 10-minute wait period and proceeds with the steps below before beginning the specimen collection as described in § 40.73.

(d) During the 10-minute wait period:

(1) Review with the employee the procedures required for a successful oral fluid specimen collection as stated in the manufacturer's instructions for the specimen collection device.

(2) Complete all items under Step 1 of the CCF, and for clarification:

(i) In Step 1.D of the CCF, the collector must put a check mark for the "Specify DOT Agency" under whose authority the test will take place.

(ii) In Step 1.G of the CCF for the "Collection Site Address", the collector must provide the address where the collection took place.

(3) The collector will provide, or the employee may select, a specimen collection device that is clean, unused, and wrapped/sealed in original packaging.

(i) The collector will check the expiration date on the device or the package containing the device and show it to the employee.

(ii) The collector must not use the device after its expiration date.

(iii) The collector must open the specimen collection device in view of the employee.

(4) The collector will complete Step 2 of the CCF.

(i) Check "Oral Fluid",

(ii) For "Oral Fluid: Split Type" check "Subdivided", and

(iii) Check "Each Device Within Expiration Date?" after ensuring the device is within its expiration date.

(5) The collector will enter the Split Specimen Device Expiration Date in Step 4 of the CCF. Since the collector will use one oral fluid device that will collect a single specimen, which is then subdivided in the presence of the donor, only one entry in Step 4 is to be made for the device expiration date.

(6) The collector must instruct the employee to use hand sanitizer or wash and dry his or her hands.

(e) To the greatest extent practicable, the collector must keep the employee's unwrapped collection device within view of both the collector and the employee, between the time the employee has provided a specimen and the specimen is sealed.

[88 FR 27642, May 2, 2023]

§ 40.73 How is an oral fluid specimen collected?

(a) The collector must be present and maintain visual contact with the employee during the procedures outlined in this section.

(b) The collector must note any unusual behavior or appearance of the employee on the CCF. If the collector detects any conduct that clearly indicates an attempt to tamper with a specimen (*e.g.,* an attempt to bring into the collection site an adulterant or oral fluid substitute), the collector must terminate the collection and report the information to the DER so that the employer can decide whether to deem the situation a refusal.

(c) The employee and collector must complete the specimen collection in accordance with the manufacturer's instructions for the collection device.

(1) Under the observation of the collector, the employee is responsible for positioning the specimen collection device for collection.

(2) The collector must ensure the collection is performed correctly (*i.e.,* using the oral fluid device in the manner described by its manufacturer), that the collection device is working properly, and that a sufficient specimen volume is collected.

(3) If the employee states that he or she is unable to provide an oral fluid specimen or provides an insufficient specimen during the collection process, the collector must continue to make one attempt to collect, after an insufficient specimen, the collector follows the procedure in § 40.193.

(4) The collector must inspect the specimen for unusual color, presence of foreign objects or material, or other signs of tampering. If it is apparent from this inspection that the employee has tampered with the specimen, the collector must conduct a new collection.

(i) Document any unusual characteristics referenced above in the Remarks section of the CCF.

(ii) Proceed with obtaining the new oral fluid specimen from the donor. Note on the new CCF that this is another collection for the same testing event (*i.e.,* Document in the remarks section that this is Specimen 2 of 2 and include the Specimen ID number of the other specimen). Make the same notation on the CCF of the suspect specimen.

[88 FR 27642, May 2, 2023]

§ 40.74 How does the collector prepare the oral fluid specimens?

(a) The collector follows the manufacturer's instructions to package the split specimen collections.

(b) A volume of at least 1 mL of undiluted (neat) oral fluid is collected for the specimen designated as “Bottle A”, and a volume of at least 1 mL of undiluted (neat) oral fluid is collected for the specimen designated as “Bottle B”, or an otherwise sufficient amount of oral fluid is collected to permit an HHS-certified laboratory to analyze the specimen(s).

(c) In the presence of the employee, the collector places a tamper-evident seal from the CCF over the cap of each specimen container, taking care not to obstruct the expiration date on the collection containers. The collector must record the date of the collection on the tamper-evident seals, after they are affixed to the specimen containers.

(d) The collector instructs the employee to initial the tamper-evident seals on each specimen container. If the employee declines to do so, the collector must note this in the "Remarks" line of the CCF (Step 2) and complete the collection process.

[88 FR 27642, May 2, 2023]

§§ 40.75-40.78 [Reserved]

§ 40.79 How is the collection process completed?

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

(1) Direct the employee to read and sign the certification statement on Copy 2 of the CCF and provide all information required in Step 5. If the employee declines to sign the CCF or to provide any of the required information, you must note this in the "Remarks" line (Step 2) of the CCF and complete the collection. If the employee declines 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, when using other forms of the CCF as approved by the Office of Management and Budget, you must follow the procedures approved for that form.

(c) 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; 80 FR 19553, Apr. 13, 2015. Redesignated and amended at 88 FR 27641, 27643, May 2, 2023]

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 each specimen testing methodology performed 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.

[65 FR 79526, Dec. 19, 2000, as amended at 88 FR 27643, May 2, 2023]

§ 40.82 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) Opioids.

(e) Phencyclidine (PCP).

[82 FR 52244, Nov. 13, 2017. Redesignated at 88 FR 27643, May 2, 2023]

§ 40.83 How do laboratories process incoming specimens?

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

(a) You are authorized to receive only Copy 1 of the CCF. You are not authorized to receive other copies of the CCF or any copies of the alcohol testing form.

(b) You must comply with applicable provisions of the HHS Guidelines concerning accessioning and processing drug specimens.

(c) You must inspect each specimen and CCF for the following "fatal flaws":

(1) There is no CCF;

(2) In cases where a specimen has been collected, there is no specimen submitted with the CCF;

(3) There is no printed collector's name and no collector's signature;

(4) Two separate collections are performed using one CCF;

(5) The specimen ID numbers on the specimen bottle and the CCF do not match;

(6) The specimen bottle seal is broken or shows evidence of tampering, unless a split specimen can be redesignated (see paragraph (h) of this section);

(7) There is an insufficient amount of specimen in the primary bottle for analysis, unless the specimens can be redesignated (see paragraph (h) of this section).

(8) For an oral fluid collection, the collector used an expired device at the time of collection.

(9) For an oral fluid collection, if the collector failed to enter the expiration date in Step 4 of the CCF and the laboratory is unable to determine the expiration date by inspecting Bottles A and B.

(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 urine 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 § 40.40(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 specimen 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 specimen 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 specimen exists in the split specimen to conduct all appropriate primary laboratory testing.

(2) In situations outlined in paragraph (h)(1) of this section, the laboratory shall mark through the “A” and write “B,” then initial and date the change. A corresponding change shall be made to the other bottle by marking through the “B” and writing “A,” and initialing and dating the change.

(i) A notation shall be made on Copy 1 of the CCF (Step 5a) and on any laboratory internal chain of custody documents, as appropriate, for any fatal or correctable flaw.

[65 FR 79526, Dec. 19, 2000, as amended at 66 FR 41951, Aug. 9, 2001; 71 FR 49384, Aug. 23, 2006; 73 FR 35970, June 25, 2008; 75 FR 59107, Sept. 27, 2010; 82 FR 52244, Nov 13, 2017; 88 FR 27643, May 2, 2023]

§ 40.84 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.

[65 FR 79526, Dec. 19, 2000. Redesignated at 88 FR 27643, May 2, 2023]

§ 40.85 What are the cutoff concentrations for urine drug tests?

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

Initial test analyte	Initial test cutoff[1]	Confirmatory test analyte	Confirmatory test cutoff concentration
Marijuana metabolites (THCA)[2]	50 ng/mL[3]	THCA	15 ng/mL.
Cocaine metabolite (Benzoylecgonine)	150 ng/mL[3]	Benzoylecgonine	100 ng/mL.
Codeine/ Morphine	2000 ng/mL	Codeine Morphine	2000 ng/mL. 2000 ng/mL.
Hydrocodone/ Hydromorphone	300 ng/mL	Hydrocodone Hydromorphone	100 ng/mL. 100 ng/mL.
Oxycodone/ Oxymorphone	100 ng/mL	Oxycodone Oxymorphone	100 ng/mL. 100 ng/mL.
6-Acetylmorphine	10 ng/mL	6-Acetylmorphine	10 ng/mL.
Phencyclidine	25 ng/mL	Phencyclidine	25 ng/mL.
Amphetamine/ Methamphetamine	500 ng/mL	Amphetamine Methamphetamine	250 ng/mL. 250 ng/mL.
MDMA[4]/MDA[5]	500 ng/mL	MDMA MDA	250 ng/mL. 250 ng/mL.

[1] For grouped analytes (i.e., two or more analytes that are in the same drug class and have the same initial test cutoff):

Immunoassay: The test must be calibrated with one analyte from the group identified as the target analyte. The cross-reactivity of the immunoassay to the other analyte(s) within the group must be 80 percent or greater; if not, separate immunoassays must be used for the analytes within the group.

Alternate technology: Either one analyte or all analytes from the group must be used for calibration, depending on the technology. At least one analyte within the group must have a concentration equal to or greater than the initial test cutoff or, alternatively, the sum of the analytes present (i.e., equal to or greater than the laboratory's validated limit of quantification) must be equal to or greater than the initial test cutoff.

[2] An immunoassay must be calibrated with a target analyte.

[3] *Alternate technology (THCA and Benzoylecgonine):* When using an alternate technology initial test for the specific target analytes of THCA and Benzoylecgonine, the laboratory must use the same cutoff for the initial and confirmatory tests (i.e., 15 ng/mL for THCA and 100ng/mL for Benzoylecgonine).

[4] Methylenedioxymethamphetamine (MDMA).

[5] Methylenedioxyamphetamine (MDA).

(b) On an initial drug test, you must report a result below the cutoff concentration as negative. If the result is at or above the cutoff concentration, you must conduct a confirmation test.

(c) On a confirmation drug test, you must report a result below the cutoff concentration as negative and a result at or above the cutoff concentration as confirmed positive.

(d) You must report quantitative values for morphine or codeine at 15,000 ng/mL or above.

[65 FR 79526, Dec. 19, 2000, as amended at 75 FR 49862, Aug. 16, 2010; 77 FR 26473, May 4, 2012; 82 FR 52244, Nov. 13, 2017. Redesignated and amended at 88 FR 27643, May 2, 2023]

§ 40.86 What is urine 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. Redesignated at 88 FR 27643, May 2, 2023]

§ 40.87 What validity tests must laboratories conduct on primary urine specimens?

As a laboratory, when you conduct validity testing under § 40.86, 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. Redesignated and amended at 88 FR 27643, May 2, 2023]

§ 40.88 What criteria do laboratories use to establish that a urine 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 2 mg/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.

[69 FR 64867, Nov. 9, 2004. Redesignated at 88 FR 27643, May 2, 2023]

§ 40.89 What are the adulterant cutoff concentrations for initial and confirmation urine 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.

[73 FR 35970, June 25, 2008. Redesignated at 88 FR 27643, May 2, 2023]

§ 40.90 What criteria do laboratories use to establish that a urine 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 supports the invalid result, where appropriate, such as pH.

(d) As a laboratory, you must report the reason a test result is invalid.

[73 FR 35970, June 25, 2008. Redesignated at 88 FR 27643, May 2, 2023]

§ 40.91 What are the cutoff concentrations for oral fluid drug tests?

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

Table 1 to § 40.91—Oral Fluid Testing Cutoff Concentrations

Initial test analyte	Initial test cutoff[1]	Confirmatory test analyte	Confirmatory test cutoff concentration
Marijuana (THC)[2]	4 ng/mL[3]	THC	2 ng/mL.
Cocaine/Benzoylecgonine	15 ng/mL	Cocaine Benzoylecgonine	8 ng/mL. 8 ng/mL.
Codeine/Morphine	30 ng/mL	Codeine Morphine	15 ng/mL. 15 ng/mL.
Hydrocodone/Hydromorphone	30 ng/mL	Hydrocodone Hydromorphone	15 ng/mL. 15 ng/mL.
Oxycodone/Oxymorphone	30 ng/mL	Oxycodone Oxymorphone	15 ng/mL. 15 ng/mL.
6-Acetylmorphine	4 ng/mL[3]	6-Acetylmorphine	2 ng/mL.
Phencyclidine	10 ng/mL	Phencyclidine	10 ng/mL.
Amphetamine/Methamphetamine	50 ng/mL	Amphetamine Methamphetamine	25 ng/mL. 25 ng/mL.
MDMA[4]/MDA[5]	50 ng/mL	MDMA MDA	25 ng/mL. 25 ng/mL.

[1] For grouped analytes (*i.e.,* two or more analytes that are in the same drug class and have the same initial test cutoff):

Immunoassay: The test must be calibrated with one analyte from the group identified as the target analyte. The cross reactivity of the immunoassay to the other analyte(s) within the group must be 80 percent or greater; if not, separate immunoassays must be used for the analytes within the group.

Alternate technology: Either one analyte or all analytes from the group must be used for calibration, depending on the technology. At least one analyte within the group must have a concentration equal to or greater than the initial test cutoff or, alternatively, the sum of the analytes present (*i.e.,* with concentrations equal to or greater than the laboratory's validated limit of quantification) must be equal to or greater than the initial test cutoff.

[2] An immunoassay must be calibrated with the target analyte.

[3] *Alternate technology (THC and 6-AM):* The confirmatory test cutoff must be used for an alternate technology initial test that is specific for the target analyte (*i.e.,* 2 ng/mL for THC, 2 ng/mL for 6-AM).

[4] Methylenedioxymethamphetamine (MDMA).

[5] Methylenedioxyamphetamine (MDA).

[88 FR 27643, May 2, 2023]

§ 40.92 What is oral fluid 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 oral fluid. The purpose of validity testing is to determine whether certain adulterants or foreign substances were added to the oral fluid, if the oral fluid was altered.

(b) If a specimen exhibits abnormal characteristics (*e.g.,* unusual odor or color), causes reactions or responses characteristic of an adulterant during initial or confirmatory drug tests (*e.g.,* non-recovery of internal standard, unusual response), or contains an unidentified substance that interferes with the confirmatory analysis, then you may conduct validity testing.

(c) 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.

[88 FR 27643, May 2, 2023]

§ 40.93 What validity tests must laboratories conduct on primary oral fluid specimens?

As a laboratory, if you conduct validity testing under § 40.92, you must conduct it in accordance with the requirements of this section.

(a) You may test for a biomarker such as albumin or immunoglobulin G (IgG) or a test for a specific adulterant.

(b) You must follow the applicable HHS requirements for any additional validity testing.

[88 FR 27643, May 2, 2023]

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

(a) As a laboratory, when reporting a result of any kind, you must report the specimen type.

(b) You must also report the results for each primary specimen, which will fall into one of the following three categories. 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 applicable:

(i) Negative, or

(ii) For urine only, 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 applicable:

(i) Positive, with drug(s)/metabolite(s) noted, with numerical values for the drug(s) or drug metabolite(s).

(ii) Adulterated, with adulterant(s) noted, with confirmatory test values (when applicable), and with remarks(s);

(iii) For urine only, positive-dilute, with drug(s)/metabolite(s) noted, with numerical values for the drug(s) or drug metabolite(s) and with numerical values for creatinine and specific gravity;

(iv) For urine only, substituted, with confirmatory test values for creatinine and specific gravity; or

(v) For urine only, invalid result, with remark(s). Laboratories will report actual values for pH results.

(vi) For oral fluid only, invalid result, with remark(s). Laboratories must report numerical values of the specimen validity test results that support a specimen reported as invalid.

(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).

(c) 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.,* a 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) SSN or Employee ID from Step 1C of the CCF, if provided;

(F) Reason for test, if provided;

(G) Collector's name and telephone number;

(H) Date of the collection;

(I) For oral fluid only, collection device expiration date;

(J) Date received at the laboratory;

(K) Date certifying scientist released the results;

(L) Certifying scientist's name;

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

(N) 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 must 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 (*e.g., see* § 40.351).

(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.

(d) 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 or other electronic means, the electronic communication must be accessible only to authorized individuals.

(e) You must transmit test results to the MRO in a timely manner, preferably the same day that review by the certifying scientist is completed.

(f)

(1) You must provide quantitative values for confirmed positive drug test results to the MRO.

(2) You must provide numerical values that support the adulterated (when applicable) or substituted result, without a request from the MRO.

(3) You must also provide the MRO numerical values for creatinine and specific gravity for the negative-dilute urine test result, without a request from the MRO.

(g) You must provide quantitative values for confirmed positive morphine and/or codeine urine results at or below 15,000 ng/mL, and for confirmed positive morphine or codeine oral fluid results at or below 150 ng/mL.

[88 FR 27644, May 2, 2023]

§ 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.

§ 40.107 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 D of this part with respect to each specimen type for which you conduct tests 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 listed in appendix E of this part for each specimen type for which you conduct testing 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. If you withdraw or are removed from NLCP's laboratory certification during a reporting period, you must provide the aggregate statistical summary to the DOT-regulated employers and to ODAPC for the last reporting period in which you conducted DOT-regulated testing.

[65 FR 79526, Dec. 19, 2000, as amended at 73 FR 35971, June 25, 2008; 88 FR 27645, May 2, 2023]

§ 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. You must subscribe to the ODAPC list-serve at *https://www.transportation.gov/odapc/get-odapc-email-updates*. DOT agency regulations, DOT MRO Guidelines, and other materials 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.transportation.gov/odapc*).

(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 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) You must meet the requirements of paragraphs (a), (b), and (c) of this section before you begin to perform MRO functions.

(d) ***Requalification training.*** During each five-year period from the date on which you satisfactorily completed the examination under paragraph (c)(2) of this section, you must complete requalification training.

(1) This requalification training must meet the requirements of the qualification training under paragraph (c)(1) of this section.

(2) Following your completion of requalification training, 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.

(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; 75 FR 49862, Aug. 16, 2010; 82 FR 52245, Nov. 13, 2017; 88 FR 27645, May 2, 2023]

§ 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 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).

(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.

[65 FR 79526, Dec. 19, 2000, as amended at 82 FR 52245, Nov. 13, 2017; 88 FR 27645, May 2, 2023]

§ 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 of all specimen types combined.

(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; 88 FR 27645, May 2, 2023]

§ 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 results 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, 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 checkmark in the "Positive" box in Step 6 on Copy 2 of the CCF, indicate the drug(s)/metabolite(s) verified positive, and sign and date the verification statement.

(d) If you cancel a laboratory confirmed positive, adulterated, substituted, or invalid result, 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; 75 FR 59107, Sept. 27, 2010; 88 FR 27645, May 2, 2023]

§ 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]

§ 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 the you.

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

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

(b) As the MRO, 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 result that you are required to provide to third parties drug test result information and medical information affecting the performance of safety-sensitive duties that the employee gives you in the verification process without the employee's consent (see § 40.327).

(1) You must give this warning to the employee before obtaining any medical information as part of the verification process.

(2) For purposes of this paragraph (d), medical information includes information on medications or other substances affecting the performance of safety-sensitive duties that the employee reports using or medical conditions the employee reports having.

(3) For purposes of this paragraph (d), the persons to whom this information may be provided include the employer, a SAP evaluating the employee as part of the return to duty process (see § 40.293(g)), DOT, another Federal safety agency (*e.g.,* the NTSB), or any state safety agency as required by state law.

(e) You must also advise the employee that, before informing any third party about any medication the employee is using pursuant to a legally valid prescription consistent with the Controlled Substances Act, you will allow 5 business days from the date you report the verified negative result 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, in your reasonable medical judgment, a medical qualification issue or a significant safety risk remains after you communicate with the employee's prescribing physician or after 5 business days, whichever is shorter, you must follow § 40.327. If, as the MRO, you receive information that eliminates the medical qualification issue or significant safety risk, you must transmit this information to any third party to whom you previously provided information under § 40.327.

[65 FR 79526, Dec. 19, 2000, as amended at 66 FR 41952, Aug. 9, 2001; 82 FR 52245, Nov. 13, 2017; 88 FR 27645, May 2, 2023]

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

(a) As the MRO, you must verify a confirmed positive test result for marijuana, cocaine, amphetamines, semi-synthetic opioids (*i.e.,* hydrocodone, hydromorphone, oxycodone, and oxymorphone), 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. In determining whether an employee's legally valid prescription consistent with the Controlled Substances Act for a substance in these categories constitutes a legitimate medical explanation, you must not question whether the prescribing physician should have prescribed the substance.

(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).

[65 FR 79526, Dec. 19, 2000, as amended at 82 FR 52245, Nov. 13, 2017]

§ 40.139 On what basis does the MRO verify test results involving 6-acetylmorphine, codeine, and morphine?

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

(a) If the laboratory confirms 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 confirms the presence of either morphine or codeine equal to or above 15,000 ng/mL (in urine) or equal to or above 150 ng/mL (in oral fluid), you must verify the test result as 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 codeine and morphine positive results, you must verify a confirmed positive test result only if you determine that there is clinical evidence, in addition to the test, of unauthorized use of any opium, opiate, or opium derivative (*i.e.,* morphine, codeine, or heroin).

(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 codeine or morphine, 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 must not verify the test positive for codeine. The admission must be for the substance that was found through the actual drug test.)

(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.

[77 FR 26473, May 4, 2012, as amended at 82 FR 52245, Nov. 13, 2017; 88 FR 27645, May 2, 2023]

§ 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 (*i.e.,* a legally valid prescription consistent with the Controlled Substances Act), you must review and take all reasonable and necessary steps to verify the authenticity of all medical records the employee provides.

(1) You may contact the employee's physician or other relevant medical personnel for further information.

(i) If you decide to contact the employee's pharmacy to authenticate whether the prescription offered by the employee was filled by the pharmacy, you or staff under your operational control can contact the pharmacy.

(ii) If you utilize staff to perform the inquiry in paragraph (b)(1)(i) of this section, you must ensure operational control over the hiring, firing, evaluation of the staff and you must oversee the performance of the function of contacting a pharmacy to authenticate specific prescription(s) (*e.g.,* outline or script what the staff will ask the pharmacy; occasionally monitor calls to assure quality control; or other methods to ensure the staff are properly conducting the calls with the pharmacies).

(2) You may request an HHS-certified laboratory with validated protocols (*see* § 40.81(c)) to conduct testing for D,L stereoisomers of amphetamine and methamphetamine or testing for tetrahydrocannabivarin (THC–V) when verifying lab results, as you determine necessary.

[65 FR 79526, Dec. 19, 2000, as amended at 82 FR 52245, Nov. 13, 2017; 88 FR 27645, May 2, 2023]

§ 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 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 criteria 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 drug 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 urine 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; 88 FR 27646, May 2, 2023]

§ 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 (verbal or written information) from any drug tests 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, 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 collection 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, 6–AM, MDMA, or MDA in a specimen.

(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 a urine specimen for which the creatinine level is below the laboratory's limit of detection. 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; 75 FR 49863, Aug. 16, 2010; 88 FR 27646, May 2, 2023]

§ 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(b), 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. Recommend to the employer that an alternate specimen should be collected if practicable (*e.g.,* oral fluid, if the specimen was urine).

(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.

(6) When the test result is invalid because pH is greater than or equal to 9.0 but less than or equal to 9.5 and the employee has no other medical explanation for the pH, you should consider whether there is evidence of elapsed time and increased temperature that could account for the pH value.

(i) You are authorized to consider the temperature conditions that were likely to have existed between the time of collection and transportation of the specimen to the laboratory, and the length of time between the specimen collection and arrival at the laboratory.

(ii) You may talk with the collection site and laboratory to discuss time and temperature issues, including any pertinent information regarding specimen storage.

(iii) If you determine that time and temperature account for the pH value, you must cancel the test and take no further action, as provided at paragraph (a)(4) of this section.

(iv) If you determine that time and temperature fail to account for the pH value, you must cancel the test and direct another collection under direct observation, as provided at paragraph (a)(5) of this section.

(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; 75 FR 49863, Aug. 16, 2010; 88 FR 27646, May 2, 2023]

§ 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 (or a legible copy of Copy 3–5) of the CCF and enter the reason on the "Remarks" line. If you do not have Copy 2 (or a legible copy of Copy 3–5), then enter "Test Cancelled" and the reason for the cancellation on a report in the format required under § 40.163(c).

(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" laboratory 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. If you do not have Copy 2 (or a legible copy of Copy 3–5), then enter "Test Cancelled" and the reason for the cancellation on a report in the format required under § 40.163(c).

[65 FR 79526, Dec. 19, 2000, as amended at 88 FR 27646, May 2, 2023]

§ 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(g) when any verified non-negative result is also invalid.

[73 FR 35972, June 25, 2008, as amended at 82 FR 52245, Nov. 13, 2017]

§ 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 SSN or employee ID No.;

(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) If you use a written report as provided in paragraph (c) of this section to report results, you must retain a copy of the written report. If you use the electronic data file to report negatives, as provided in paragraph (d) of this section, you must retain a retrievable copy of that report in a format suitable for inspection and

audit by a DOT representative. In either case, you must keep the completed Copy 2 of the CCF. When completing Copy 2, either the MRO must sign and date it (for both negatives and non-negatives) or MRO staff must stamp and date it (for negatives only).

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

(g) You must not provide quantitative values to the DER or C/TPA for drug or validity test results. However, you must provide the test information in your possession to a SAP who consults with you (see § 40.293(g)).

(h) You must maintain reports and records related to negatives and cancelled results for one year; you must maintain reports and records related to positives and refusals for five years, unless otherwise specified by applicable DOT agency regulations.

[66 FR 41952, Aug. 9, 2001, as amended at 75 FR 49863, Aug. 16, 2010; 75 FR 59107, Sept. 27, 2010; 76 FR 59578, Sept. 27, 2011; 88 FR 27646, May 2, 2023]

§ 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.

§ 40.171—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.

[65 FR 79526, Dec. 19, 2000, as amended at 82 FR 52245, Nov. 13, 2017]

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 35972, 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) confirmed in the primary specimen.

(b) You must conduct this test without regard to the cutoff concentrations of § 40.85 or § 40.91, as applicable.

(c) If the test fails to reconfirm the presence of the drug(s)/drug metabolite(s) that were reported 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 § 40.87 or § 40.93, as applicable.

(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 35972, June 25, 2008; 88 FR 27646, May 2, 2023]

§ 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 § 40.89 or § 40.93, as applicable 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.

[73 FR 35973, June 25, 2008, as amended at 88 FR 27646, May 2, 2023]

§ 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 a urine split specimen, you must test the split specimen using the confirmatory tests for creatinine and specific gravity, using the criteria set forth in § 40.88.

[88 FR 27646, May 2, 2023]

§ 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 at 73 FR 35972, 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 F 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 (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 F 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 F 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 F to this part.

(f) For all split specimen results, as the MRO you must in Step 7 of Copy 2 of the CCF:

(1) Report split specimen test results by checking the “Reconfirmed” box and/or the “Failed to Reconfirm” box, or the “Test Cancelled” box, as appropriate.

(2) , Enter your name, sign, and date.

(3) 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.

[73 FR 35973, June 25, 2008, as amended at 75 FR 59108, Sept. 27, 2010; 88 FR 27646, May 2, 2023]

§ 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.

§ 40.153—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.

[65 FR 79526, Dec. 19, 2000, as amended at 82 FR 52245, Nov. 13, 2017]

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 collection site before the testing process commences (*see* § 40.63(c) or § 40.72(e), as applicable) for a pre-employment test is not deemed to have refused to test. The collector is not required to inform an employee that the failure to remain at the collection site is a refusal. If an employee leaves prior to the completion of the testing process, per § 40.355(i) the employer must decide whether the employee's actions constitute a refusal;

(3) Fail to provide a specimen for any drug test required by this part or DOT agency regulations. Provided that an employee who does not provide a specimen because he or she has left the testing site before the testing process commences (*see* § 40.63(c) or § 40.72(e), as applicable) for a pre-employment test is not deemed to have refused to test. The collector is not required to inform an

employee that the failure to remain at the collection site is a refusal. If an employee leaves prior to the completion of the testing process, per § 40.355(i) the employer must decide whether the employee's actions constitute a refusal;

(4) In the case of a directly observed or monitored urine collection in a drug test, fail to permit the observation or monitoring of an employee's provision of a specimen (*see* §§ 40.67(m) and 40.69(g));

(5) Fail to provide a sufficient amount of specimen 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) as applicable);

(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(c). 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;

(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, fail to remove objects from mouth, fail to permit inspection of the oral cavity, or fail to complete a rinse when requested);

(9) For an observed urine 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; or

(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. The consequences specified under DOT agency regulations for a refusal cannot be overturned or set aside by an arbitration, grievance, State court or other non-Federal forum that adjudicates the personnel decisions the employer has taken against the employee.

(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 actions that may constitute a refusal in the "Remarks" line (Step 2), and sign and date the CCF. The collector does not make the final decision about whether the employee's conduct constitutes a refusal to test; the employer has the sole responsibility to decide whether a refusal occurred, as stated in § 40.355(i), the employer has a non-delegable duty to make the decision about whether the employee has refused to test.

(2) As the MRO, you must note the refusal by checking the "Refusal to Test" box in Step 6 on Copy 2 of the CCF, checking whether the specimen was adulterated or substituted and, if adulterated, noting the adulterant/reason. If there was another reason for the refusal, check "Other" in Step 6 on Copy 2 of the CCF, and note the reason next to the "Other" box and on the "Remarks" lines, as needed. You must then sign and date the CCF.

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

[65 FR 79526, Dec. 19, 2000, as amended at 66 FR 41953, Aug. 9, 2001; 68 FR 31626, May 28, 2003; 71 FR 49384, Aug. 23, 2006; 73 FR 35974, June 25, 2008; 75 FR 59108, Sept. 27, 2010; 88 FR 27647, May 2, 2023]

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

(a) If an employee does not provide a sufficient amount of specimen to permit a drug test (*i.e.,* 45 mL of urine in a single void, or 2mL oral fluid in a single sampling, as applicable) you, as the collector, must provide another opportunity to the employee to do so. In accordance with the employer's instructions, this can be done using the same specimen type as the original collection or this can be done by a collector qualified to use an alternate specimen collection for this purpose.

(1) If you change to an alternate specimen collection at this point (*i.e.,* from urine to oral fluid; or from oral fluid to urine), the next collection begins under § 40.61(e) for urine or § 40.72 for oral fluid collection.

(i) If you proceed with an alternate specimen collection, discard the insufficient specimen and proceed with the next specimen collection.

(ii) If you proceed with an alternate specimen collection, discard the CCF for the insufficient specimen and begin a new CCF for the next specimen collection with a notation in the remarks section of the new CCF.

(b)

(1) As the collector, you must do the following when continuing with a urine specimen collection under this section:

(i) 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)).

(ii) 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.

(iii) 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 that fact on the "Remarks" line of the CCF (Step 2), and immediately notify the DER of the conduct as provided in § 40.191(e)(1); the employer decides whether the situation is deemed to be a refusal.

(iv) 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. You must also discard any specimen the employee previously provided, including any specimen that is "out of temperature range" or shows signs of tampering. In the remarks section of the CCF that you will distribute to the MRO and DER, note the fact that the employee provided an "out of temperature range specimen" or "specimen that shows signs of tampering" and that it was discarded because the employee did not provide a second sufficient specimen.

(2) As the collector, you must do the following when continuing with an oral fluid specimen collection under this section:

(i) If the employee demonstrates an inability to provide a specimen after 15 minutes of using the collection device, and if the donor states that he or she could provide a specimen after drinking some fluids, urge the employee to drink (up to 8 ounces) and wait an additional 10 minutes before beginning the next specimen collection (a period of up to one hour must be provided, or until the donor has provided a sufficient oral fluid specimen, whichever occurs first). If the employee simply needs more time before attempting to provide an oral fluid specimen, the employee is not required to drink any fluids during the one-hour wait time. It is not a refusal to test if the employee declines to drink. The employee must remain at the collection site, in a monitored area designated by the collector, during the wait period.

(ii) If the employee has not provided a sufficient specimen within one hour 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.

(3) 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, if the collector informs you that the employee has not provided a sufficient amount of specimen (*see* paragraph (b) 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 urine (*see* paragraph (b)(1) of this section) or oral fluid (*see* paragraph (b)(2) of this section) sufficient specimen, but not both. The evaluation and MRO determination required by this section only applies to the oral fluid or the urine insufficient specimen that was the final methodology at the collection site. (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 specimen 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 specimen. 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 specimen. As the MRO, if you accept this recommendation, you must:

(i) Check the “Refusal to Test” box and “Other” box in Step 6 on Copy 2 of the CCF and note the reason next to the “Other” box and on the “Remarks” lines, as needed.

(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 in the case of a urine test or autoimmune disorder in the case of an oral fluid test), 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, return-to-duty, or follow-up 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 specimen 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 specimen. 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. If the test reason was 'random', the employee remains in the random testing pool.

[88 FR 27647, May 2, 2023]

§ 40.195 What happens when an individual is unable to provide a sufficient amount of specimen

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 urine 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, as amended at 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 CCF;

(2) In cases where a specimen has been collected, there is no specimen submitted with the CCF;

(3) There is no printed collector's name and no collector's signature;

(4) Two separate collections are performed using one CCF;

(5) The specimen ID numbers on the specimen bottle and the CCF do not match;

(6) The specimen bottle seal is broken or shows evidence of tampering (and a split specimen cannot be re-designated, see § 40.83(h)); or

(7) Because of leakage or other causes, there is an insufficient amount of specimen in the primary specimen bottle for analysis and the specimens cannot be re-designated (*see* § 40.83(h)).

(8) For an oral fluid collection, the collector used an expired device at the time of collection.

(9) For an oral fluid collection, the collector failed to enter the expiration date in Step 4 of the CCF and the laboratory confirmed that the device was expired.

(c) You must report the result as provided in § 40.161.

[65 FR 79526, Dec. 19, 2000, as amended at 82 FR 52245, Nov. 13, 2017; 88 FR 27648, May 2, 2023]

§ 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 specimen. 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; 88 FR 27648, May 2, 2023]

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

(a) As the MRO, when a laboratory discovers a "correctable flaw" during its processing of incoming specimens (see § 40.83), the laboratory will attempt to correct it. If the laboratory is unsuccessful in this attempt, it will report to you that the specimen has been "Rejected for Testing" (with the reason stated).

(b) The following is a "correctable flaw" that laboratories must attempt to correct: The collector's signature is omitted on the certification statement on the CCF.

(c) As the MRO, when you discover a "correctable flaw" during your review of the CCF, you must cancel the test unless the flaw is corrected.

(d) The following are correctable flaws that you must attempt to correct:

(1) The employee's signature is omitted from the certification statement, unless the employee's failure or refusal to sign is noted on the "Remarks" line of the CCF.

(2) The certifying scientist's signature is omitted on Copy 1 of the CCF for a positive, adulterated, substituted, or invalid test result.

(3) The collector uses a non-Federal form or an expired CCF for the test. This flaw may be corrected through the procedure set forth in § 40.205(b)(2), provided that the collection testing process has been conducted in accordance with the procedures in this part in an HHS-certified laboratory.

[65 FR 79526, Dec. 19, 2000, as amended at 66 FR 41954, Aug. 9, 2001; 75 FR 59108, Sept. 27, 2010; 76 FR 59578, Sept. 27, 2011; 82 FR 52246, Nov. 13, 2017]

§ 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).

(d) If a test is cancelled for a correctible flaw (*i.e.,* § 40.203 or § 40.205), only the MRO who cancelled the test can reverse the cancellation and must do so within 60 days of the cancellation. After 60 days, the MRO who cancelled the test cannot reverse the cancellation without the permission of ODAPC. For example, if an MRO cancels a test because the MRO did not receive a copy of the CCF, but later receives a copy of the

CCF, the MRO may reverse the decision to cancel the test within 60 days. After 60 days, the MRO must contact ODAPC for permission to reverse the cancellation. An MRO must not reverse the cancellation of a test that the laboratory has reported as rejected for testing, as described in § 40.83(g). A laboratory is not authorized to reverse a cancellation due to a fatal flaw, as described in § 40.199.

[65 FR 79526, Dec. 19, 2000, as amended at 73 FR 35975, June 25, 2008; 88 FR 27648, May 2, 2023]

§ 40.208 What problems require corrective action but do 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 any of the following omissions listed in paragraphs (a)(1) through (3) of this section occurred, you must take corrective action, including securing a memorandum for the record explaining the problem and taking appropriate action to ensure the problem does not recur:

(1) For a urine collection, 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; or

(2) For an oral fluid collection, the collector failed to check the box in Step 2 of the CCF that indicates "Each Device was Within Expiration Date" but the collector entered the "Split Specimen Device Expiration Date" in Step 4 of the CCF.

(3) For an oral fluid collection, the collector erred by entering the expiration date as the "Primary/Single Specimen Device Expiration Date" instead of entering the date as the "Split Specimen Device Expiration Date" in Step 4 of the CCF.

(b) The errors listed in paragraph (a) of this section do not result in the cancellation of the test.

(c) As an employer or service agent, the errors listed in paragraph (a) of this section, 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.

[88 FR 27649, May 2, 2023]

§ 40.209 What procedural problems do not result in the cancellation of a test and do not require correction?

(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 SSN or Employee ID No., the omission of the DOT Agency in Step 1–D of the CCF.)

(2) An error that does not affect employee protections under this part (*e.g.,* the collector's failure to add bluing agent to the toilet bowl, which adversely affects only the ability of the collector to detect tampering with the specimen by the employee);

(3) The collection of a specimen by a collector who is required to have been trained (*see* § 40.33 or 40.35), 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 § 40.42;

(8) If the specific name of the courier on the CCF is omitted or erroneous;

(9) Personal identifying information is inadvertently contained on the CCF (*e.g.,* the employee signs his or her name on Copy 1); or

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

(11) The failure to use a new CCF for a second collection after an insufficient specimen was conducted under a different methodology (*e.g.,* failing to use a new CCF for an oral fluid test after an insufficient quantity of urine was produced on a urine test.)

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

[65 FR 79526, Dec. 19, 2000, as amended at 66 FR 41954, Aug. 9, 2001; 75 FR 59108, Sept. 27, 2010; 88 FR 27649, May 2, 2023]

§ 40.210 What kinds of drug tests are permitted under the regulations?

Both urine and oral fluid specimens are authorized for collection and testing under this part. An employer can use one or the other, but not both at the beginning of the testing event. For example, if an employee is sent for a test, either a urine or oral fluid specimen can be collected, but not both simultaneously. However, if there is a problem in the collection that necessitates a second collection (*e.g.,* insufficient quantity of urine, temperature out of range, or insufficient saliva), then a different specimen type could be chosen by the employer (*i.e.,* through a standing order or a discussion with the collector) or its service agent (*i.e.,* if there is no standing order and the service agent cannot contact the DER) to complete the collection process for the testing event. Only urine and oral fluid specimens screened and confirmed at HHS-certified laboratories (*see* § 40.81) are allowed for drug testing under this part. Point-of-collection (POC) urine, POC oral fluid drug testing, hair testing, or instant tests are not authorized.

[88 FR 27649, May 2, 2023]

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) You must be knowledgeable about the alcohol testing procedures in this part and the current DOT guidance. Procedures and guidance 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.transportation.gov/odapc*). You must keep current on any changes to these materials. You must subscribe to the ODAPC list-serve at (*https://www.transportation.gov/odapc/get-odapc-email-updates*).

(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) You must meet the requirements of paragraphs (b) and (c) of this section before you begin to perform STT or BAT functions.

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

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

(1) Error correction training must be provided and your proficiency documented in writing by a person who meets the requirements of paragraph (b)(4) of this section.

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

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

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

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

(1) Anyone meeting the requirements of this section to be a BAT may act as an STT, provided that the individual has demonstrated initial proficiency in the operation of the ASD that he or she is using, as provided in paragraph (c) of this section.

(2) Law enforcement officers who have been certified by state or local governments to conduct breath alcohol testing are deemed to be qualified as BATs. They are not required to also complete the training requirements of this section in order to act as BATs. In order for a test conducted by such an officer to be accepted under DOT alcohol testing requirements, the officer must have been certified by a state or local government to use the EBT or ASD that was used for the test.

[65 FR 79526, Dec. 19, 2000, as amended at 66 FR 41954, Aug. 9, 2001; 75 FR 5244, Feb. 2, 2010; 82 FR 52246, Nov. 13, 2017]

§ 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 I to this part. You may view this form on the ODAPC web site (*http://www.transportation.gov/odapc*).

(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 8529, Feb. 25, 2010; 75 FR 13009, Mar. 18, 2010; 82 FR 52246, Nov. 13, 2017; 88 FR 27649, May 2, 2023]

§ 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?

ASDs listed on ODAPC's Web page for “Approved Screening Devices to Measure Alcohol in Bodily Fluids” and EBTs listed on ODAPC's Web page for “Approved Evidential Breath Measurement Devices” are the only devices you are allowed to use to conduct alcohol screening tests under this part. You may use an ASD 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 must not be used for confirmation tests.

[82 FR 52246, Nov. 13, 2017]

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

(a) EBTs on ODAPC's Web page for “Approved Evidential Breath Measurement 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.

(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.

[65 FR 79526, Dec. 19, 2000, as amended at 82 FR 52246, Nov. 13, 2017]

§ 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 ODAPC places the EBT on its Web page for "Approved Evidential Breath Measurement Devices."

(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)(3).

(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.

[65 FR 79526, Dec. 19, 2000, as amended at 82 FR 52246, Nov. 13, 2017]

§ 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 approves it and ODAPC places the device on its Web page for "Approved Screening Devices to Measure Alcohol in Bodily Fluids". 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 .

[65 FR 79526, Dec. 19, 2000, as amended at 82 FR 52246, Nov. 13, 2017]

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]

§ 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 collection site before the testing process commences (*see* § 40.243(a)) for a pre-employment test is not deemed to have refused to test. The BAT or STT is not required to inform an employee that the failure to remain at the collection site is a refusal. If an employee leaves prior to the completion of the testing process, per § 40.355(i) the employer must decide whether the employee's actions constitute a refusal;

(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. The BAT or STT is not required to inform an employee that the failure to remain at the collection site is a refusal. If an employee leaves prior to the completion of the testing process, per § 40.355(i) the employer must decide whether the employee's actions constitute a refusal;

(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. The consequences specified under DOT agency regulations for a refusal cannot be overturned or set aside by an arbitration, grievance, State court or other non-Federal forum that adjudicates the personnel decisions the employer has taken against the employee.

(c)

(1) 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).

(2) As the BAT or STT, you must note the actions that may constitute a refusal in the "Remarks" line (Step 3), and sign and date the ATF. The BAT or STT does not make the final decision about whether the employee's conduct constitutes a refusal to test; the employer has the sole responsibility to decide whether a refusal occurred, as stated in § 40.355(i), the employer has a non-delegable duty to make the decision about whether the employee has refused to test.

(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; 88 FR 27649, May 2, 2023]

§ 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 itermediary). You must not include in this statement detailed information on the employee's medical condition beyond what is necessary to explain your conclusion.

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

§ 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]

§ 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, as 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 an organization listed at *https://www.transportation.gov/odapc/sap*.

(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. You must keep current on any changes to these materials. You must subscribe to the ODAPC list-serve at *https://www.transportation.gov/odapc/get-odapc-email-updates*. DOT agency regulations, DOT SAP Guidelines, and other materials 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.transportation.gov/odapc*).

(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) You must meet the requirements of paragraphs (a), (b), and (c) of this section 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.

(f) ***Limitation.*** If you are an otherwise qualified SAP under this part, you must abide by the geographic limitations applicable to your credential when performing remote evaluations. You must not conduct an evaluation that exceeds your geographic limitations.

[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; 82 FR 52246, Nov. 13, 2017; 88 FR 27649, May 2, 2023]

§ 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 G 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; 88 FR 27650, May 2, 2023]

§ 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 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.

[65 FR 79526, Dec. 19, 2000, as amended at 88 FR 27650, May 2, 2023]

§ 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 clinical assessment and evaluation to determine what assistance is needed by the employee to resolve problems associated with alcohol and/or drug use. At the SAP's discretion, this assessment or evaluation may be performed face-to-face in-person or remotely. If a SAP is not prohibited from using technology within the parameters of the SAP's State-issued license or other credential(s), a remote evaluation must be must be conducted in accordance with the following criteria:

(i) The technology must permit real-time audio and visual interaction between the SAP and the employee; and

(ii) The quality of the technology (*e.g.,* speed of the internet connection and clarity of the video display) must be sufficient to allow the SAP to gather all the visual and audible information the SAP would otherwise gather in an in-person face-to-face interaction, while providing security to protect the confidentiality of the communications at the level expected by industry standards for remote substance abuse evaluations.

(2) Referring the employee to an appropriate education and/or treatment program;

(3) Conducting a 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. This assessment or evaluation may be performed face-to-face in-person or remotely. A face-to-face remote evaluation must meet the criteria in paragraphs (a)(1)(i) and (ii) of this section.

(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.

[65 FR 79526, Dec. 19, 2000, as amended at 88 FR 27650, May 2, 2023]

§ 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 assessment and clinical evaluation meeting the requirements of § 40.291(a)(1).

(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 assess and clinically evaluate each employee on an individual basis and use your professional judgment to determine education and/or treatment, as well as a follow-up testing plan unique to the needs of the individual employee. For example, do not require the same and/or substantially similar education, treatment, and/or follow-up testing plan for most of the employees you assess.

(f) You must provide a written report directly to the DER highlighting your specific recommendations for assistance (see § 40.311(c)).

(g) 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.

(h) 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.

[65 FR 79526, Dec. 19, 2000, as amended at 88 FR 27650, May 2, 2023]

§ 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).

(c) The SAP, who is otherwise fully qualified under this subpart, must not perform evaluations outside the geographic jurisdiction for their credential(s). If the SAP who made the evaluation exceeds their geographic jurisdiction, the employee will not be required to seek the evaluation of a second SAP.

[65 FR 79526, Dec. 19, 2000, as amended at 88 FR 27650, May 2, 2023]

§ 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 an 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 clinical interview meeting the requirements of § 40.291(a)(1) 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.

[65 FR 79526, Dec. 19, 2000, as amended at 88 FR 27650, May 2, 2023]

§ 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.

(d) As the employer, if a SAP who is otherwise fully qualified under this subpart performed a remote evaluation of the employee outside the geographic jurisdiction for their credential(s), the employee who they evaluated will not be required to seek the evaluation of a second SAP. If you decide that you want to permit the employee to return to the performance of safety-sensitive functions, you will proceed with the requirements of paragraph (a) of this section.

[65 FR 79526, Dec. 19, 2000, as amended at 88 FR 27650, May 2, 2023]

§ 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.

(g) As the employer, SAP, or other service agent, you must not provide to the employee a copy of their drug and/or alcohol follow-up testing schedule prescribed by the SAP. No employer, SAP, or other service agent will indicate to the employee what the frequency or duration of the employee's follow-up testing schedule will be. The SAP can require follow-up testing for either or both drugs and alcohol for a drug-related or an alcohol-related violation.

[65 FR 79526, Dec. 19, 2000, as amended at 88 FR 27650, May 2, 2023]

§ 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 or employee ID No.;

(2) Employer's name and address;

(3) Reason for the assessment (specific violation of DOT regulations and violation date);

(4) Date(s) and format (*i.e.,* face-to-face or remote) 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 or employee ID No.;

(2) Employer's name and address;

(3) Reason for the initial assessment (specific violation of DOT regulations and violation date);

(4) Date(s) and format (*i.e.,* face-to-face or remote) 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 or employee ID No.;

(2) Employer's name and address;

(3) Reason for the initial assessment (specific DOT violation and date);

(4) Date(s) and format (*i.e.,* face-to-face or remote) 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.

[65 FR 79526, Dec. 19, 2000, as amended at 88 FR 27650, May 2, 2023]

§ 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 (d) 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) The MRO must not report such medical information using the CCF. Instead, the MRO must provide the information in a separate written communication (*e.g.,* letter, secure email). The information must state the specific nature of the MRO's safety concern (*e.g.,* the effects of a medication the employee is taking, the employee's underlying medical condition that the employee disclosed to the MRO).

(d) 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.

[65 FR 79526, Dec. 19, 2000, as amended at 88 FR 27650, May 2, 2023]

§ 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. DNA testing and other types of identity testing are not authorized and ODAPC will not give permission for such testing. 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; 82 FR 52247, Nov. 13, 2017]

§ 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 H 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.

[65 FR 79526, Dec. 19, 2000, as amended at 88 FR 27650, May 2, 2023]

§ 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 Copy 1 of the CCF. You must not transmit other copies of the CCF or any ATFs to the laboratory.

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

(n) You must not intentionally delay the transmission of drug or alcohol testing-related documents concerning actions you have performed, because of a payment dispute or other reasons.

> *Example 1 to paragraph (n):* A laboratory that has tested a specimen must not delay transmitting the documentation of the test result to an MRO because of a billing or payment dispute with the MRO or a C/TPA.

> *Example 2 to paragraph (n):* An MRO or SAP who has interviewed an employee must not delay sending a verified test result or SAP report to the employer because of such a dispute with the employer or employee.

> *Example 3 to paragraph (n):* A collector who has performed a 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; 71 FR 49384, Aug. 23, 2006; 75 FR 59108, Sept. 27, 2010; 88 FR 27650, May 2, 2023]

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 interviews meeting the requirements of § 40.291(a)(1);

(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, falsely representing that the service agent or its activities is approved or certified by the Department or a DOT agency (such representation includes, but is not limited to, the use of a Department or DOT agency logo, title, or emblem).

(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).

[65 FR 79526, Dec. 19, 2000, as amended at 82 FR 52247, Nov. 13, 2017; 88 FR 27650, May 2, 2023]

§ 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?

At 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?

The Director makes his or her decision within 60 days of the date when the record of a PIE proceeding is complete (including any meeting with the Director and any additional fact-finding that is necessary). The Director may extend this period for good cause for additional periods of up to 30 days.

§ 40.399 How does the Department notify service agents of its decision?

If you are a service agent involved in a PIE proceeding, the Director provides you written notice as soon as he or she makes a PIE decision. The notice includes the following elements:

(a) If the decision is not to issue a PIE, a statement of the reasons for the decision, including findings of fact with respect to any material factual issues that were in dispute.

(b) If the decision is to issue a PIE—

(1) A reference to the NOPE;

(2) A statement of the reasons for the decision, including findings of fact with respect to any material factual issues that were in dispute;

(3) A statement of the scope of the PIE; and

(4) A statement of the duration of the PIE.

§ 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.transportation.gov/odapc*) . 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.

[65 FR 79526, Dec. 19, 2000, as amended at 82 FR 52247, Nov. 13, 2017]

§ 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?

The Director's decision is a final administrative action of the Department. Like all final administrative actions of Federal agencies, the Director's decision is subject to judicial review under the Administrative Procedure Act (5 U.S.C. 551 *et. seq*).

§ 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 stop using the services of the service agent no later than 90 days after the Department has published the decision in the FEDERAL REGISTER or posted it on its web site. You may apply to the ODAPC Director for an extension of 30 days if you demonstrate that you cannot find a substitute service agent within 90 days.

(c) Except during the period provided in paragraph (b) of this section, you must not, as an employer, use the services of a service agent that are covered by a PIE that the Director has issued under this subpart. If you do so, you are in violation of the Department's regulations and subject to applicable DOT agency sanctions (*e.g.,* civil penalties, withholding of Federal financial assistance).

(d) You also must not obtain drug or alcohol testing services through a contractor or affiliate of the service agent to whom the PIE applies.

> *Example to paragraph (d):* Service Agent R was subject to a PIE with respect to SAP services. As an employer, not only must you not use R's own SAP services, but you also must not use SAP services you arrange through R, such as services provided by a subcontractor or affiliate of R or a person or organization that receives financial gain from its relationship with R.

(e) This section's prohibition on using the services of a service agent concerning which the Director has issued a PIE applies to employers in all industries subject to DOT drug and alcohol testing regulations.

> *Example to paragraph (e):* The initiating official for a PIE was the FAA drug and alcohol program manager, and the conduct forming the basis of the PIE pertained to the aviation industry. As a motor carrier, transit authority, pipeline, railroad, or maritime employer, you are also prohibited from using the services of the service agent involved in connection with the DOT drug and alcohol testing program.

(f) The issuance of a PIE does not result in the cancellation of drug or alcohol tests conducted using the service agent involved before the issuance of the Director's decision or up to 90 days following its publication in the FEDERAL REGISTER or posting on the Department's web site, unless otherwise specified in the Director's PIE decision or the Director grants an extension as provided in paragraph (b) of this section.

Example to paragraph (f): The Department issues a PIE concerning Service Agent N on September 1. All tests conducted using N's services before September 1, and through November 30, are valid for all purposes under DOT drug and alcohol testing regulations, assuming they meet all other regulatory requirements.

§ 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—Oral Fluid Collection Kit Contents

1. Oral Fluid Collection Device

a. A single device, which can be subdivided in the employee's presence into an “A” specimen and a “B” split specimen bottle sufficient for laboratory testing, that is either of the following:

(1) An oral fluid collection device made to collect a sufficient amount of oral fluid to permit an HHS-certified laboratory to analyze the specimen(s). For example, a device that directs the oral fluid into two separate collection bottles.

(2) A device that uses buffering solution that collects a specimen using a single pad or dual pads joined for insertion together into the same region of the mouth, which can be subdivided into two separate collection bottles. Such a buffered device may use a diluent (or other component, process, or method that modifies the volume of the testable specimen). The volume specifications for the device must be consistent with those set by HHS.

b. Must have unit markings or other indicators that demonstrate the adequacy of the volume of oral fluid specimen collected.

c. Must be sufficiently transparent to permit a visual assessment of the contents without opening the specimen bottle.

d. Must be individually packaged in an easily visible tamper-evident system.

e. Must have the device's expiration date on the specimen bottles sent to the laboratory (*i.e.,* the shortest expiration date of any component).

f. Must not have components that substantially affect the composition of drugs and/or drug metabolites in the oral fluid specimen and/or interfere with an accurate analysis of the specimen.

g. Must maintain the integrity of the specimen during storage and transport so the specimen can be tested in an HHS-certified laboratory.

h. Must be designed so that the required tamper-evident bottle seals made available on the CCF fit without concealing the expiration date on the bottles, without damage to the seal when the collector dates and the employee initials it.

i. Must be approved by HHS for use by the specific HHS-certified laboratory that will test the specimen gathered by this device.

2. Instructions

Must include the manufacturer's instructions within the device's packaging. The instructions must provide sufficient detail to allow for an error-free collection when the instructions are followed.

3. Leak-Resistant Plastic Bag

a. Must have two sealable compartments or pouches that are leak-resistant; one large enough to hold two specimen bottles and the other large enough to hold the CCF paperwork, as applicable.

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 damage during shipment of the 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 collection device sent to collection sites.

c. A shipping container is not necessary if a laboratory courier hand-delivers the specimen bottles in the leak-resistant plastic bags from the collection site to the laboratory.

[88 FR 27651, May 2, 2023]

Appendix C to Part 40 [Reserved]

Appendix D to Part 40—DOT Drug Testing Semi-Annual Laboratory Report to Employers

The following items are required on each laboratory 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)

A. Urine Specimens

1. Urine Specimen Results Reported (Total Number) By Test Reason

(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. Urine Specimens Reported

(a) Negative (number)

(b) Negative and Dilute (number)

3. Urine Specimens Reported as Rejected for Testing (Total Number) by Reason

(a) Fatal flaw (number)
(b) Uncorrected Flaw (number)

4. Urine Specimens Reported as Positive (Total Number) by Drug

(a) Marijuana Metabolite (number)
(b) Cocaine Metabolite (number)
(c) Opioids (number)
    (1) Codeine (number)
    (2) Morphine (number)
    (3) 6–AM (number)
    (4) Hydrocodone (number)
    (5) Hydromorphone (number)
    (6) Oxycodone (number)
    (7) Oxymorphone (number)
(d) Phencyclidine (number)
(e) Amphetamines (number)
    (1) Amphetamine (number)
    (2) Methamphetamine (number)
    (3) MDMA (number)
    (4) MDA (number)

5. Urine Adulterated (Number)

6. Urine Substituted (Number)

7. Urine Invalid Result (Number)

B. Oral Fluid Specimens

1. Oral Fluid Specimen Results Reported (Total Number) by Test Reason

(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. Oral Fluid Specimens Reported

(a) Negative (number)

(b) Negative and Dilute (number)

3. Oral Fluid Specimens Reported as Rejected for Testing (Total Number) by Reason

(a) Fatal flaw (number)

(b) Uncorrected Flaw (number)

4. Oral Fluid Specimens Reported as Positive (Total Number) by Drug

(a) Marijuana (number)

(b) Cocaine and/or Cocaine Metabolite (number)

(c) Opioids (number)

(1) Codeine (number)

(2) Morphine (number)

(3) 6–AM (number)

(4) Hydrocodone (number)

(5) Hydromorphone (number)

(6) Oxycodone (number)

(7) Oxymorphone (number)

(d) Phencyclidine (number)

(e) Amphetamines (number)

(1) Amphetamine (number)

(2) Methamphetamine (number)

(3) MDMA (number)

(4) MDA (number)

5. Oral Fluid Adulterated (Number)

6. Oral Fluid Substituted (Number)

7. Oral Fluid Invalid Result (Number)

[88 FR 27651, May 2, 2023]

Appendix E to Part 40—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, 1200 New Jersey Avenue SE, 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. Specimen Type:

—oral fluid or urine

2. DOT agency

—FMCSA, FAA, FRA, FTA, PHMSA, or USCG

3. Test Reason

—Pre-Employment, Random, Reasonable Suspicion/Cause, Post-Accident, Return-to-Duty, Other, and Follow-up

A. DOT Specimen Results Reported (total number)

B. Negative Results Reported (total number)

1. Negative (number)
2. Negative-Dilute (number)

C. Rejected for Testing Results Reported (total number) By Reason

1. Fatal flaw (number)
2. Uncorrected Flaw (number)

D. Positive Results Reported (total number) By Drug

1. Marijuana or Marijuana Metabolite (number)
2. Cocaine and/or Cocaine Metabolite (number)
3. Opioids (number)
    a. Codeine (number)
    b. Morphine (number)
    c. 6–AM (number)
    d. Hydrocodone (number)
    e. Hydromorphone (number)
    f. Oxycodone (number)
    g. Oxymorphone (number)
4. Phencyclidine (number)
5. Amphetamines (number)

a. Amphetamine (number)
b. Methamphetamine (number)
c. MDMA (number)
d. MDA (number)

E. Adulterated Results Reported (total number) By Reason (number)
F. Substituted Results Reported (total number)
G. Invalid Results Reported (total number) By Reason (number)

[88 FR 27652, May 2, 2023]

Appendix F 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, 1200 New Jersey Avenue SE, Washington, DC 20590.

Fax: (202) 366–3897.

Submit Electronically: https://www.transportation.gov/odapc/mro-split-specimen-cancellation-notification.

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. Specimen type.
6. Laboratory accession number.
7. Primary specimen laboratory name, address, and phone number.
8. Date result reported or certified by primary laboratory.
9. Split specimen laboratory name, address, and phone number.
10. Date split specimen result reported or certified by split specimen laboratory.
11. Primary specimen results (*e.g.,* name of drug, adulterant) in the primary specimen.
12. Reason for split specimen failure-to-reconfirm result (*e.g.,* drug or adulterant not present, specimen invalid, split not collected, insufficient volume).
13. Actions taken by the MRO (*e.g.,* notified employer of failure to reconfirm and requirement for re-collection).
14. Additional information explaining the reason for cancellation.
15. Name of individual submitting the report (if not the MRO).

[88 FR 27652, May 2, 2023]

Appendix G 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.

[65 FR 79526, Dec. 19, 2000. Redesignated at 88 FR 27651, May 2, 2023]

Appendix H 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(e): 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)–(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. Redesignated and amended at 88 FR 27651, 27652, May 2, 2023]

Appendix I to Part 40—Alcohol Testing Form

The following form is the alcohol testing form required for use in the DOT alcohol testing program beginning January 1, 2011. Employers are authorized to use the form effective 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, Sate, 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 information provided on the form 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 technician must complete their owa form.) I certify that I have conducted alcohol testing on the above named individual in accordance with the procedures established in the US Department of Transportation regulation, 49 CFR Part 40, that I am qualified to operate the testing device(s) identified, and that the results are as recorded.

TECHNICIAN: BAT STT DEVICE: SALIVA BREATH* 15-Minute Wait: Yes No

SCREENING TEST: *(For 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 drive, perform safety-sensitive 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 information provided on the form 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 technician must complete their own form.) I certify that I have conducted alcohol testing on the above named individual in accordance with the procedures established in the US Department of Transportation regulation, 49 CFR Part 40, that I am qualified to operate the testing device(s) identified, and that the results are as recorded.

TECHNICIAN: ☐ BAT ☐ STT DEVICE: ☐ SALIVA ☐ BREATH* 15-Minute Wait: ☐ Yes ☐ No

SCREENING TEST: *(For BREATH DEVICE* write in the space below only if the testing device is not designed to print.)*

Test #	Testing Device Name	Device Serial # OR Lot # & Exp Date	Activation Time	Reading Time	Result

CONFIRMATION TEST: *Results MUST be affixed to each copy of this form or printed directly onto the form.*

REMARKS:

_____
_____
_____

_____ _____
Alcohol Technician's Company Company Street Address

_____ _____ (___) _____
(PRINT) Alcohol Technician's Name (First, M.I., Last) Company City, State, Zip Phone Number

_____ ___/___/___
Signature of Alcohol Technician Date Month Day Year

Print Additional Results Here or Affix With Tamper Evident Tape

STEP 4: TO BE COMPLETED BY EMPLOYEE IF TEST RESULT IS 0.02 OR HIGHER

I certify that I have submitted to the alcohol test, the results of which are accurately recorded on this form. I understand that I must not drive, perform safety-sensitive duties, or operate heavy equipment because the results are 0.02 or greater.

_____ ___/___/___
Signature of Employee Date Month Day Year

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 information provided on the form 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 technician must complete their own form.) I certify that I have conducted alcohol testing on the above named individual in accordance with the procedures established in the US Department of Transportation regulation, 49 CFR Part 40, that I am qualified to operate the testing device(s) identified, and that the results are as recorded.

TECHNICIAN: ☐ BAT ☐ STT DEVICE: ☐ SALIVA ☐ BREATH* 15-Minute Wait: ☐ Yes ☐ No

SCREENING TEST: *(For BREATH DEVICE* write in the space below only if the testing device is not designed to print.)*

Test #	Testing Device Name	Device Serial # OR Lot # & Exp Date	Activation Time	Reading Time	Result

CONFIRMATION TEST: *Results MUST be affixed to each copy of this form or printed directly onto the form.*

REMARKS:

_____

_____

_____

_____ _____
Alcohol Technician's Company Company Street Address

_____ _____ ( )
(PRINT) Alcohol Technician's Name (First, M.I., Last) Company City, State, Zip Phone Number

_____ ____/____/____
Signature of Alcohol Technician Date Month Day Year

Print Additional Results Here or Affix With Tamper Evident Tape

STEP 4: TO BE COMPLETED BY EMPLOYEE IF TEST RESULT IS 0.02 OR HIGHER

I certify that I have submitted to the alcohol test, the results of which are accurately recorded on this form. I understand that I must not drive, perform safety-sensitive duties, or operate heavy equipment because the results are 0.02 or greater.

_____ ____/____/____
Signature of Employee Date Month Day Year

Form DOT F 1380 (Rev. 5/2008) OMB No. 2105-0529

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.

[75 FR 8529, Feb. 25, 2010, as amended at 75 FR 13009, Mar. 18, 2010; 75 FR 38423, July 2, 2010. Redesignated at 88 FR 27651, May 2, 2023]

Appendix J 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 to report calendar year MIS data. The instructions for this form are found at *https://www.transportation.gov/odapc*.

U.S. DEPARTMENT OF TRANSPORTATION DRUG AND ALCOHOL TESTING MIS DATA COLLECTION FORM

Calendar Year Covered by this Report: _____

OMB No. 2105-0529

Form DOT F 1385 (Rev. 4/2019)

I. Employer:

Company Name: _____

Doing Business As (DBA) Name (if applicable): _____

Address: _____ E-mail: _____

Name of Certifying Official: _____ Signature: _____

Telephone: (____) _____ Date Certified: _____

Prepared by (if different): _____ Telephone: (____) _____

C/TPA Name and Telephone (if applicable): _____ (____) _____

Check the DOT agency for which you are reporting MIS data; and complete the information on that same line as appropriate:

___ FMCSA – Motor Carrier: DOT #: _____ Owner-operator: (circle one) YES or NO Exempt (Circle One) YES or NO

___ FAA – Aviation: Certificate # (if applicable): _____ Plan / Registration # (if applicable): _____

___ PHMSA – Pipeline: (Check) Gas Gathering__ Gas Transmission__ Gas Distribution__ Transport Hazardous Liquids__ Transport Carbon Dioxide__

___ FRA – Railroad: Total Number of observed/documented Part 219 "Rule G" Observations for covered employees: _____

___ USCG – Maritime: Vessel ID # (USCG- or State-Issued): _____ (If more than one vessel, list separately.)

___ FTA – Transit

II. Covered Employees: (A) Enter Total Number Safety-Sensitive Employees In All Employee Categories:

(B) Enter Total Number of Employee Categories:

(C)

Employee Category	Total Number of Employees in this Category

If you have multiple employee categories, complete Sections I and II (A) & (B). Take that filled-in form and make one copy for each employee category and complete Sections II (C), III, and IV for each separate employee category.

III. Drug Testing Data:

	1	2	3	4	5	6	7	8	9	10	11	12	13
									Refusal Results				
Type of Test	Total Number Of Test Results [Should equal the sum of Columns 2, 3, 9, 10, 11, and 12]	Verified Negative Results	Verified Positive Results – For One Or More Drugs	Positive For Marijuana	Positive For Cocaine	Positive For PCP	Positive For Opioids	Positive For Amphetamines	Adulterated	Substituted	"Shy Bladder" – With No Medical Explanation	Other Refusals To Submit To Testing	Canceled Results
Pre-Employment													
Random													
Post-Accident													
Reasonable Susp./Cause													
Return-to-Duty													
Follow-Up													
TOTAL													

IV. Alcohol Testing Data:

	1	2	3	4	5	6	7	8	9
							Refusal Results		
Type of Test	Total Number Of Screening Test Results [Should equal the sum of Columns 2, 3, 7, and 8]	Screening Tests With Results Below 0.02	Screening Tests With Results 0.02 Or Greater	Number Of Confirmation Tests Results	Confirmation Tests With Results 0.02 Through 0.039	Confirmation Tests With Results 0.04 Or Greater	"Shy Lung" – With No Medical Explanation	Other Refusals To Submit To Testing	Canceled Results
Pre-Employment									
Random									
Post-Accident									
Reasonable Susp./Cause									
Return-to-Duty									
Follow-Up									
TOTAL									

PAPERWORK REDUCTION ACT NOTICE (as required by 5 CFR 1320.21)

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 90 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.

Title 18, USC Section 1001, makes it a criminal offense subject to a maximum fine of $10,000, or imprisonment for not more than 5 years, or both, to knowingly and willfully make or cause to be made any false or fraudulent statements of representations in any matter within the jurisdiction of any agency of the United States.

[84 FR 16773, Apr. 23, 2019. Redesignated at 88 FR 27651, May 2, 2023]

Title 49 —Transportation
Subtitle B —Other Regulations Relating to Transportation
Chapter VI —Federal Transit Administration, Department of Transportation

PART 655—PREVENTION OF ALCOHOL MISUSE AND PROHIBITED DRUG USE IN TRANSIT OPERATIONS

Authority: 49 U.S.C. 5331 (as amended); 49 CFR 1.91

Source: 66 FR 42002, Aug. 9, 2001, unless otherwise noted.

Subpart A—General

§ 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 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.

§ 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.

§ 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 49 U.S.C. 5307, 5309, or 5311; and

(2) Any contractor of a recipient or subrecipient of Federal assistance under 49 U.S.C. 5307, 5309, 5311.

(b) A recipient operating a railroad regulated by the Federal Railroad Administration (FRA) shall follow 49 CFR Part 219 and § 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; 78 FR 37993, June 25, 2013]

§ 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 public transportation vehicle involved is a rail car, trolley car, trolley bus, or vessel, the public transportation 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 § 655.82 and § 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 public 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 a person that receives Federal financial assistance under 49 U.S.C. 5307, 5309, or 5311 directly from the Federal Government.

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 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 public transportation vehicle is a vehicle used for public 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; 78 FR 37993, June 25, 2013]

§ 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, 1200 New Jersey Ave., SE, Washington, DC 20590.

(d) The Administrator may grant a waiver subject to 49 CFR 40.21(d).

[66 FR 42002, Aug. 9, 2001, as amended at 88 FR 27653, May 2, 2023]

§ 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.

§ 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

§ 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.

§ 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 § 655.15. Each employer shall disseminate the policy consistent with the provisions of § 655.16.

(b) An education and training program which meets the requirements of § 655.14.

(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.

§ 655.13 [Reserved]

§ 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.

§ 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 prohibited 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 § 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.

[66 FR 42002, Aug. 9, 2001, as amended at 88 FR 27653, May 2, 2023]

§ 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.

§ 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.

§§ 655.18-655.20 [Reserved]

Subpart C—Prohibited Drug Use

§ 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) Opioids;

(4) Amphetamines; and

(5) Phencyclidine.

(c) Consumption of these products is prohibited at all times.

[66 FR 42002, Aug. 9, 2001, as amended at 84 FR 16775, Apr. 23, 2019]

§§ 655.22-655.30 [Reserved]

Subpart D—Prohibited Alcohol Use

§ 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.

§ 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.

§ 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.

§ 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 § 655.44 for eight hours following the accident or until he or she undergoes a post-accident alcohol test, whichever occurs first.

§ 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 of this part from taking any action otherwise consistent with law.

§§ 655.36-655.40 [Reserved]

Subpart E—Types of Testing

§ 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 § 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.

§ 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.

§ 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 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.

§ 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 public transportation 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 § 382.303.

(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 public transportation vehicle is involved, the employer shall drug and alcohol test each covered employee operating the public transportation 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, 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.

[66 FR 42002, Aug. 9, 2001, as amended at 78 FR 37993, June 25, 2013; 88 FR 27653, May 2, 2023]

§ 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 § 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 § 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 § 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 § 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 § 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 § 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 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.

§ 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.

§ 655.47 Follow-up testing after returning to duty.

An covered employer shall conduct follow-up testing of each employee who returns to duty, as specified in 49 CFR Part 40, subpart O.

[66 FR 42002, Aug. 9, 2001, as amended at 88 FR 27653, May 2, 2023]

§ 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 § 655.35. The covered employee may not perform safety-sensitive functions unless the confirmation alcohol test result is less than 0.02.

§ 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 § 655.44, a random drug and alcohol test required under § 655.45, a reasonable suspicion drug and alcohol test required under § 655.43, or a follow-up drug and alcohol test required under § 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.

§ 655.50 [Reserved]

Subpart F—Drug and Alcohol Testing Procedures

§ 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.

§ 655.52 Substance abuse professional (SAP).

The SAP must perform the functions in 49 CFR Part 40.

§ 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 or oral fluid collector, breath alcohol technician, or saliva-testing technician for a drug or alcohol test of the employee.

[66 FR 42002, Aug. 9, 2001, as amended at 88 FR 27653, May 2, 2023]

§§ 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.

(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 a covered 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.

[66 FR 42002, Aug. 9, 2001, as amended at 87 FR 27653, May 2, 2023]

§ 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.

§§ 655.63-655.70 [Reserved]

Subpart H—Administrative Requirements

§ 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 oral fluid or breath 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.

[66 FR 42002, Aug. 9, 2001, as amended at 87 FR 27653, May 2, 2023]

§ 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 (MIS) form and instructions as required by 49 CFR part 40, § 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]

§ 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 § 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.

(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.

§§ 655.74-655.80 [Reserved]

Subpart I—Certifying Compliance

§ 655.81 Grantee oversight responsibility.

A recipient shall ensure that a subrecipient or contractor who receives 49 U.S.C. 5307, 5309, or 5311 funds directly from the recipient complies with this part.

[78 FR 37993, June 25, 2013]

§ 655.82 Compliance as a condition of financial assistance.

(a) A recipient shall not be eligible for Federal financial assistance under 49 U.S.C. 5307, 5309, or 5311, if a recipient fails to establish an anti-drug and alcohol misuse program in compliance with this part.

(b) If the Administrator determines that a recipient that receives Federal financial assistance under 49 U.S.C. 5307, 5309, or 5311 is not in compliance with this part, the Administrator may bar the recipient from receiving Federal financial assistance in an amount the Administrator considers appropriate.

(c) A recipient is subject to criminal sanctions and fines for false statements or misrepresentations under 18 U.S.C. 1001.

(d) Notwithstanding § 655.3, a recipient operating a ferryboat regulated by the USCG who fails to comply with the USCG chemical and alcohol testing requirements, shall be in noncompliance with this part and may be barred from receiving Federal financial assistance in an amount the Administrator considers appropriate.

[78 FR 37993, June 25, 2013]

§ 655.83 Requirement to certify compliance.

(a) A recipient of Federal financial assistance under section 5307, 5309, or 5311 shall annually certify compliance with this part 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) Recipients, including a State, that administers 49 U.S.C. 5307, 5309, or 5311 Federal financial assistance to subrecipients and contractors, shall annually certify compliance with the requirements of this part, on behalf of its applicable subrecipient or contractor to the applicable FTA Regional Office. A recipient administering section 5307, 5309, or 5311 Federal funding may suspend a subrecipient or contractor from receiving Federal transit funds for noncompliance with this part.

[66 FR 42002, Aug. 9, 2001, as amended at 71 FR 69198, Nov. 30, 2006; 78 FR 37993, June 25, 2013]

ATTACHMENT C

ORANGE COUNTY TRANSPORTATION AUTHORITY

DRUG AND ALCOHOL POLICY MANUAL

July 2018 Revision

HSEC

COMMITMENT • ACCOUNTABILITY
RESPONSIVENESS • ENGAGEMENT

HEALTH, SAFETY &
ENVIRONMENTAL COMPLIANCE

ACKNOWLEDGEMENT OF RECEIPT OF OCTA DRUG AND ALCOHOL POLICY MANUAL

I, the undersigned, have received a copy of the Orange County Transportation Authority (OCTA or Authority) Drug and Alcohol Policy Manual, which complies with the Federal Transit Administration (FTA) and U.S. Department of Transportation (DOT) regulations, 49 CFR Part 40 and Part 655 as amended. I understand that nothing in this publication is intended to supplement, alter or serve as an official interpretation of 49 CFR Part 40 or DOT agency regulations.

I understand and acknowledge that compliance with this Policy is a condition of my employment and that if I violate any provision of this Policy I will be subject to disciplinary action, which may include termination of employment. Further, I understand that it is my responsibility to read, understand and comply with the Drug and Alcohol Policy Manual.

_____ _____

Employee Name (Print) Employee Badge #

_____

Employee Signature

_____

Date

2018 REVISION

The Orange County Transportation Authority (OCTA or Authority) Drug and Alcohol Policy Manual complies with the Federal Transit Administration (FTA) and U.S. Department of Transportation (DOT) regulations, 49 CFR Part 40 and Part 655, as amended, which regulates standards for the collection and mandated testing of breath and urine specimens. The purpose of this manual is to outline the most common processes in relationship to the DOT/ FTA regulations. Nothing in this publication is intended to supplement, alter or serve as an official interpretation of 49 CFR Part 40 and Part 655 or DOT agency regulations.

Additionally, the DOT enacted The Drug-Free Workplace Act of 1988 (DFWA) which required the establishment of drug-free workplace policies and the reporting of certain drug-related offenses to the FTA. The Authority's Drug-Free Workplace Act Certification is included in this Policy as Attachment D and additional information about the Drug-Free Awareness Program is provided in Section 7.

This Drug and Alcohol Policy Manual incorporates federal requirements in addition to OCTA requirements. To distinguish DOT and/or FTA requirements from OCTA-specific requirements, portions of the Policy text have been **bolded when references are made to the inclusion of non-safety-sensitive position employees or other OCTA-specific policy**. The organization takes pride in achieving and maintaining high results with regulatory compliance and employee compliance with OCTA mandated policies. OCTA mandated policies are in addition to the required processes and are chosen to enhance the overall performance results of the Authority.

The Authority acknowledges a strong commitment to the health and well-being of employees. Any OCTA employee or employee's family members who may be experiencing the pressures and/or problems of substance abuse, and/or related problems, is urged to seek help through Resources For Living, the Authority's Employee Assistance Program (EAP). The EAP provides strictly confidential services and counseling. To contact the EAP directly, call (866) 370-4838. You may also visit the Resources For Living Website at www.mylifevalues.com. Services are available 24 hours a day, 7 days a week.

Each OCTA employee is provided a copy of this Policy and acknowledges receipt of the Policy by signing an Acknowledgement of Receipt of OCTA Drug and Alcohol Policy Manual Attachment G. It is the responsibility of all OCTA employees to read, understand, and comply with the Drug and Alcohol Policy Manual.

DRUG AND ALCOHOL POLICY MANUAL

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DRUG AND ALCOHOL POLICY MANUAL

GENERAL OVERVIEW—SECTION 1

1.1 POLICY STATEMENT

Orange County Transportation Authority (OCTA) has a vital interest in providing its employees with safe and healthful working conditions and providing its riders and the public with high quality public transportation that is effective, safe, and efficient. The Authority will not tolerate any drug or alcohol use which may affect job performance or pose a hazard to the safety and welfare of the employee, the public, other employees, or the Authority.

In addition, OCTA encourages employees to become knowledgeable on potential impairment when using over-the-counter (OTC) or prescription (Rx) medication. The intention is to reduce potential safety risks by removing impairment in the workplace, regardless of the source.

The Authority is committed to establishing and maintaining a safe and healthy work environment free from the influence of drugs and alcohol. With this objective in mind, the Authority has established the following Policy with regard to the use, possession, sale, manufacture, distribution, or dispensation of drugs and alcohol.

This Policy complies with the Federal Transit Administration (FTA) regulations, U.S. Department of Transportation (DOT) standards and The Drug-Free Workplace Act of 1988 (DFWA). **The OCTA Drug and Alcohol Policy Manual has in some areas broadened the FTA and DOT requirements by including non-safety sensitive positions, as well as safety-sensitive positions, in some areas of testing.**

1.2 APPLICABILITY

The Drug and Alcohol Policy Manual applies to all introductory, regular full-time and part- time safety-sensitive positions and some portions also apply **to non-safety sensitive positions, including temporary, extra help, interns, or as-needed employees, volunteers, and contractors when they are on OCTA property or when performing any OCTA business.** OCTA's Policy standards for employees in safety-sensitive positions include the requirements of the DOT, as discussed in Policy Statement Section 1.1.

Visitors, vendors, and contractors are governed by this Policy while on OCTA premises and will not be permitted to conduct business or remain on OCTA grounds if found to be in violation of this Policy.

1.3 RESERVATION OF RIGHTS

The Authority reserves the right to interpret, change or rescind the provisions of this policy that are not required by federal law, in whole or in part and without notice.

1.4 CONDITION OF EMPLOYMENT

Compliance with the Authority's Drug and Alcohol Policy Manual is a condition of employment for all **employees**. Failure or refusal of **an employee** to cooperate fully, submit to an inspection or test, or follow any prescribed course of substance abuse treatment is grounds for employment termination.

1.5 INSPECTIONS

When there is reason to believe that an employee or group of employees may be in possession of alcohol or illegal drugs on Authority property, the employee(s) is (are) required, as a condition of employment, to submit to reasonable inspections, including but not limited to: clothing, personal containers, lockers, company vehicles, purses, lunch boxes, briefcases or other containers, desks, or personal vehicles (while on Authority property). An inspection must be authorized by the Department Manager or higher-level management personnel. Whenever possible, the searches also should be approved by the Department Management of Labor and Employee Relations Department. If the Department Manager of Labor and Employee Relations cannot be reached, the Department Manager of Human Resources may approve a search.

1.6 CONVICTION OF A DRUG RELATED OFFENSE

Please see Conviction of a Drug Related Offense Policy.

Responsibilities
Section 2

DRUG AND ALCOHOL POLICY MANUAL

RESPONSIBILITIES—SECTION 2

2.1 EMPLOYEES

Employees at all levels are responsible for reading, understanding, and adhering to this Policy. Each employee shall receive and sign an Acknowledgment of Receipt of OCTA Drug and Alcohol Policy Attachment G. Any employee who violates this policy is subject to disciplinary action up to and including employment termination.

2.2 MANAGERS AND SUPERVISORS

Managers and Supervisors will be held strictly accountable for the consistent application, enforcement, and adherence of the Policy. Any Manager/Supervisor who knowingly disregards the requirements of this Policy, or who is found to deliberately misuse the Policy in regard to any employee, or personally fails to adhere to the Policy, shall be subject to discipline up to and including employment termination.

2.3 RESPONSIBLE DEPARTMENT

The Health, Safety, and Environmental Compliance Department is responsible for the administration of this Policy, including the retention of Acknowledgement of Receipt forms Attachment G. The Designated Employer Representative maintains all Attachment B forms and is the liaison between the Authority and the Medical Review Officer (MRO). Employees who have questions regarding this Policy may direct their questions to Health, Safety, and Environmental Compliance staff Attachment F.

DRUG AND ALCOHOL POLICY MANUAL

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ALCOHOL GUIDELINES—SECTION 3

3.1 ALCOHOL CONSUMPTION

The possession, consumption, **or sale of any amount** of alcoholic beverage while at work, **on Authority property**, **doing business on behalf of the Authority, in an Authority vehicle, or in an Authority uniform (including breaks, lunch, and non-work hours)** is prohibited **for all employees**. Additionally, alcohol use by an employee in a safety-sensitive position is prohibited at any time while he/she is on duty or subject to be on duty. **Employees must refrain from alcohol consumption within a minimum of at least eight (8) hours of reporting to work or during the hours that he/she is subject to duty and must be clear of the effects of alcohol.**

Alcohol use by an employee in a non-safety-sensitive position while performing Authority business, while on Authority property, in an Authority vehicle, or in Authority uniform (including breaks, lunch, and non-work hours) is prohibited to the extent that such alcohol may have a material, adverse effect on the safety of that employee, co-workers, riders, or members of the general public, the employee's job performance, or the safe, efficient operation of the Authority's facilities or the Authority's image.

Alcohol use by any employee (whether or not in a safety-sensitive position) is prohibited at any time he/she is driving an Authority vehicle (including revenue service and non-revenue service vehicles).

3.1A OFF-THE-JOB ALCOHOL CONSUMPTION

Off-the-job alcohol use and/or activity, which could reasonably have an adverse effect on an employee's job performance or which could jeopardize the safety of the employee, other employees, riders, the general public, or Authority equipment, or which could reflect unfavorably on the Authority's relationship with the public, is proper cause for disciplinary action up to and including termination of employment. Of course, off-the-job use of drugs or alcohol which results in an employee being under the influence of drugs or alcohol while on duty is considered "on-the-job" use of drugs or alcohol and will be treated accordingly.

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Drug Guidelines
Section 4

DRUG AND ALCOHOL POLICY MANUAL

DRUG GUIDELINES—SECTION 4

4.1 ILLEGAL DRUG USE

The consumption, **sale, purchase, offer to sell or purchase, transfer, possession, manufacture, distribution, or dispensation** of an illegal drug **by an employee while in an Authority facility, in an Authority vehicle, on Authority property, while in Authority uniform (including breaks, lunch, and non-work hours), or** while performing Authority business is strictly prohibited. The presence of any amount of an illegal drug or its metabolites in **any employee** while performing Authority business, **in an Authority facility**, **in an Authority vehicle, in Authority uniform, or on Authority property** is prohibited.

No employee shall bring drug paraphernalia, which is used in the storage, concealment, injection, ingestion, or consumption of illegal drugs, onto Authority premises or property or into Authority vehicles.

Illegal drug means any drug (a) which is not legally obtainable or (b) which is legally obtainable but has not been legally obtained. The term includes, but is not limited to, marijuana, cocaine, opiates, amphetamines, methamphetamines, and phencyclidine (see Section 5.4 for identified threshold levels for each prohibited drug).

4.2 LEGAL DRUG USE

The use or being under the influence of a legal drug by any employee, while performing Authority business or while on Authority property, is prohibited to the extent that such use or influence may have a material, adverse effect on the safety of the employee, co-workers, riders, or members of the public, the employee's job performance, the safe and efficient operation of the Authority's facilities, or the Authority's image.

Employees in safety-sensitive positions are required to report the use of any legal prescription drug or over-the-counter drug as defined in sections 4.2A-4.2C.

4.2A ATTACHMENT B FOR PRESCRIPTION DRUG USE

An employee in a safety-sensitive position must properly complete an Attachment B form for any legal drug taken which may cause drowsiness or which may otherwise impair, to any extent, the employee's ability to safely and efficiently perform his/her job; and for any controlled substance taken which is identified in Schedule 1 (21 CFR 1308.11), an amphetamine, a narcotic, or any other habit forming drug,

unless the legal drug(s) is prescribed by a licensed medical practitioner familiar with the employee's medical history and assigned duties and who completes the physician's portion of the Attachment B indicating that the drug will not adversely affect the employee's ability to safely operate a commercial motor vehicle. Attached to the Attachment B is a copy of the job description summaries for safety-sensitive positions.

It is each employee's responsibility to know and to not engage in any safety-sensitive duties without express written consent from a physician if any legal drug prescribed by his/her doctor:

- **May cause drowsiness or otherwise impair your ability to safely and efficiently perform your job duties;**
- **Is a drug listed on Schedule I, attached for your reference to the Attachment B form;**
- **Is an amphetamine;**
- **Is a narcotic; or**
- **Is a habit forming drug.**

It is required that you bring a copy of the Attachment B form, with its Exhibits, to your doctor and ask your doctor if the drug(s) you are being prescribed falls into one or more of the above categories.

To properly complete the Attachment B form, an employee in a safety-sensitive position is required to (1) have his/her doctor complete and sign side 1 of the Attachment B form and attach a copy of the prescription or bottle label with the employee's name on it; (2) sign at the bottom of side 1 of the form in the Employee section; and (3) submit the completed form to the Health, Safety, and Environmental Compliance Department in a confidential envelope within one working day of taking the prescription drug.

4.2B ATTACHMENT B FOR OVER-THE-COUNTER DRUGS

An employee in a safety-sensitive position must properly complete an Attachment B form for any legal over-the-counter (OTC) drug taken that contains a warning label on the packaging which indicates that the drug may cause drowsiness or otherwise impair the employee's ability to safely perform job duties. An employee in a safety-sensitive position may not engage in any safety-sensitive functions while taking any

legal OTC drug that contains a warning label on the packaging which indicates that the drug may cause drowsiness or otherwise impair the employee's ability to safely perform job duties.

To adhere to the Drug and Alcohol Policy for legal OTC drugs, an employee in a safety-sensitive position is required to (1) complete and sign side 2 of the Attachment B form, (2) sign at the bottom of side 2 of the form in the Employee section; and (3) submit the completed form to the Health, Safety, and Environmental Compliance Department in a confidential envelope within one working day of taking the OTC drugs.

4.2C AFTER COMPLETING THE ATTACHMENT B FORM

After completion of an employee's Attachment B form and review of the form by the Health, Safety, and Environmental Compliance Department, the Health, Safety, and Environmental Compliance Department will review the form for completeness and file. Questions about a legal Rx/OTC drug may be discussed with OCTA's Medical Review Officer (MRO). The Authority retains the right to place an employee on a medical hold while the MRO is reviewing the employee's Attachment B. The Authority, in its discretion, may request the MRO to issue an independent decision as to whether an employee in a safety-sensitive position may work while taking a legal Rx/OTC drug. The Authority may request at any time such an independent decision, which will be binding on the employee, for any employee in a safety-sensitive position who is working or intends to work while taking a legal Rx/OTC drug.

If the MRO determines that an employee in a safety-sensitive position should not work while taking the legal Rx/OTC drug, the employee may be required to take a leave of absence or comply with other appropriate action/direction. An employee may obtain an independent opinion from his/her physician regarding the use of a legal Rx/OTC drug. In order to continue working in this situation, an employee must have his/her doctor complete side 1 of the Attachment B form and submit a completed Attachment B form to the Health, Safety, and Environmental Compliance Department, in a confidential envelope, for authorization prior to returning to work.

If an employee fails to adhere to the Drug and Alcohol Policy regarding the taking of a legal Rx/OTC drug in accordance with these provisions or fails to complete an Attachment B form for each legal Rx/OTC drug taken by the employee or obtain the physician's signature for prescription drugs, the employee will be subject to discipline, including termination.

DRUG AND ALCOHOL POLICY MANUAL

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Testing
Section 5

DRUG AND ALCOHOL POLICY MANUAL

TESTING—SECTION 5

5.1 DRUG AND ALCOHOL TESTING

Under this Policy, drug and alcohol testing shall be conducted when circumstances warrant or may be required by applicable law or regulations **or as required by OCTA policy**. The Authority's drug and alcohol testing will be performed in compliance with DOT regulations 49 CFR 40 and Part 655, as amended. Accordingly, a positive drug or alcohol test administered under this Policy is a violation of this Policy and will result in disciplinary action, up to and including termination.

The Authority has selected testing sites that conducts testing following CFR Part 40 processes and procedures and that have a high degree of accuracy and reliability and use techniques, equipment, and laboratory facilities which have been approved by the US Department of Health and Human Services.

Any employee who refuses to comply with a request for testing, who refuses to sign any **OCTA required testing form**, who provides false information in connection with a test, or who attempts to falsify test results through tampering, contamination, adulteration, or substitution will be considered to have a positive test and shall be subject to discharge proceedings.

The purpose of this section is to outline the most common processes in relationship to 49 CFR Part 40 or DOT agency regulations. It does not serve as a document to outline or define all the requirements with 49 CFR Part 40 or DOT agency regulations.

5.2 PRIVACY STATEMENT

The privacy of the employee will be protected. The integrity and validity of the test process will be maintained, and the drug testing laboratories are required to maintain employee test records in confidence. The drug testing laboratories shall disclose information to the MRO, and the MRO in turn notifies the Designated Employer Representative (DER). OCTA will adhere to all standards of confidentiality regarding employee testing. Test records and results may be released by the DER to those authorized to receive such information by the FTA rules and/or federal, state, or local agency requirements. Testing records and results may be released by the Authority to: the employee, if requested by the employee in writing; the National Transportation Safety Board when investigating an accident; the decision maker in a lawsuit, grievance, or other proceeding initiated on behalf of the employee; representatives of OCTA in a lawsuit, grievance, or other proceedings; subsequent employers of a safety-sensitive position employee.

5.3 ALCOHOL TESTING

Tests for alcohol concentration will be conducted utilizing a National Highway Traffic Safety Administration (NHTSA) approved Evidential Breath Testing (EBT) device operated by a qualified Breath Alcohol Technician (BAT). Under DOT regulations, an employee in a safety-sensitive position with an alcohol concentration of 0.02 or greater but less than 0.04, shall not be permitted 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 (8) hours following administration of the test. **Under OCTA Policy, if the initial test indicates an alcohol concentration of 0.001 to .02, a second non-DOT alcohol test will be performed to confirm the results of the initial test. A confirmed alcohol concentration greater than 0.000 will be considered a positive test and a violation of this Policy.**

Any employee who is unable to provide the required volume of breath without a valid, verified medical reason will be considered to have refused the test and will be in violation of this Policy.

5.4 DRUG TESTING

Drug testing consists of a two-stage process utilizing a urine sample collected under the split specimen method. First, a screening test using an immunoassay technique is performed. If the screening test is positive for one or more drugs, a confirmation test is performed for each identified drug using state-of-the-art gas chromatography/mass spectrometry (GC/MS) analysis. The appropriate Custody and Control forms (CCF) will be used throughout the process according to the type of test identified in Attachment E.

Pursuant to the DOT and FTA regulations **and OCTA standards**, the drugs or classes of drugs to be tested and the applicable threshold levels for positive findings shall be determined by current DOT and FTA regulations.

5.5 TYPES OF TESTING

5.5A DOT PRE-EMPLOYMENT (POST-OFFER) OR TRANSFER TO SAFETY-SENSITIVE POSITION

The Authority will conduct pre-employment (post-offer) **physical examinations** and testing designed to prevent hiring persons for safety-sensitive positions who use illegal drugs and/ or persons whose use of **alcohol or** legal drugs indicates a potential for impaired or unsafe job performance. An individual will not be hired for a safety-sensitive position unless the individual passes a drug and alcohol test administered in accordance with this Policy.

An employee who will be transferred or promoted to a safety-sensitive position must first pass a drug and alcohol test administered in accordance with this Policy. Employees who are interested in such transfer or promotion will be required to provide a written consent to participate in the Transfer to a Safety-Sensitive Position Testing. Employees who do not provide this written consent will not be allowed to perform safety-sensitive functions.

An employee who has not performed a safety-sensitive duty for 90 consecutive days or more and has not been in the Authority's random selection pool shall take a Pre-Employment drug and **alcohol** test with a verified negative result before returning to safety-sensitive duties.

5.5B DOT REASONABLE SUSPICION/NON-DOT PROBABLE CAUSE

The Authority will require a drug and/or an alcohol test of **any employee** who is reasonably suspected of violating this Policy, including but not limited to, **any employee** suspected of **possessing**, using, or being under the influence of alcohol or an illegal drug, a legal drug if such use would violate this Policy, while on duty **or in Authority vehicles or on Authority property or in Authority uniform.**

The request to undergo a reasonable suspicion test will be based on specific contemporaneous, articulable observations by at least one Supervisor trained on the physical, behavioral, speech, and performance indicators of probable drug and alcohol misuse. **It is recommended that two (2) trained Supervisors make the reasonable suspicion referral whenever possible**. Reasonable suspicion/**probable cause** alcohol testing is only permissible just before an employee performs duties, during that performance, and just after an employee has performed safety-sensitive duties. Employees will be required to proceed immediately with a supervisor to a collection site following a reasonable suspicion/**probable cause** determination. If an alcohol test is delayed beyond two (2) hours, reason(s) for the delay must be documented. After eight (8) hours, cease all attempts and document reason(s) for inability to test.

Examples of reasonable suspicion/**probable cause** include, but are not limited to the following:

- Physical signs and symptoms consistent with prohibited substance use (illegally used controlled substance or drugs under the Drug-Free Workplace Act), or misuse of alcohol (e.g., odor of alcohol, slurred speech, or lack of coordination).

- **Evidence of the manufacture, distribution, dispensing, possession, or use of controlled substances, drugs, alcohol, or other prohibited substances.**

- **Occurrence of a serious or potentially serious industrial accident that may have been caused by the employee's use of drugs or alcohol.**

- **Fights (to mean physical contact), assaults, and flagrant disregard or violations of established safety, security, or other operating procedures.**

5.5C DOT POST ACCIDENT/NON-DOT POST ACCIDENT

As soon as practicable after an accident, an employee will be required to take a drug and alcohol test per the following thresholds under FTA Post Accident testing:

- Fatality – In the event of an accident involving the loss of human life, each surviving employee operating the mass transit vehicle at the time of the accident shall be required to submit to a drug and alcohol test. Any other employee whose performance could have contributed to the accident will also be required to submit to a drug and alcohol test.

- Non-Fatal Accident – Following an accident which resulted in an injury requiring immediate medical treatment away from the scene or any vehicle being towed away from the scene with disabling damage, each employee operating the mass transit vehicle at the time of the accident shall be required to submit to a drug and alcohol test, unless the employee's performance can be completely discounted as a contributing factor to the accident. Any other employee whose performance could have contributed to the accident will also be required to submit to a drug and alcohol test.

A decision as to whether to administer a drug and alcohol test after an accident will be made by a Supervisor who was not involved in the accident and based on the best information available at the time. Accident testing is delayed while **the employee** assists in the resolution of the accident or receives medical attention following the accident. Following an accident, the **employee(s)** involved shall be tested immediately, but not to exceed eight (8) hours for alcohol testing and thirty-two (32) hours for drug testing. The responding Supervisor at the

scene shall document why an alcohol test was not performed within two (2) hours of the accident, an alcohol test was not performed within eight (8) hours of the accident, or a drug test was not performed within thirty-two (32) hours of the accident. Alcohol use is prohibited by **any employee** required to take a post-accident alcohol test for eight hours following the accident or until he or she undergoes a post-accident alcohol test, whichever occurs first. **Any employee** subject to post-accident testing who fails to remain readily available for such testing, or who leaves the scene of the accident without prior authorization will be considered to have refused to submit to the test and will be subject to disciplinary action up to and including employment termination.

OCTA reserves the right to perform a non-DOT Post Accident test on an employee involved in an accident involving a mass transit or an Authority vehicle, whether or not on Authority business, which does not meet the FTA Post Accident requirements.

5.5D DOT/NON-DOT RETURN-TO-DUTY FOLLOW-UP

Generally, an employee will be terminated for violations of this Policy. However, in the event an employee is suspended or placed on a leave of absence for a violation of this Policy, he/she may not return to duty until the Substance Abuse Professional (SAP) has evaluated the employee to determine whether the employee has followed the recommendation of the SAP, including active participation and completion of a rehabilitation program and he/she passes a directly observed Return-To-Duty drug and alcohol test. The SAP will recommend follow-up testing in accordance with DOT regulations. Frequency and duration is dependent on SAP assessment of which will be a minimum of six (6) tests during twelve (12) months after return to duty of duration of up to sixty (60) months.

Additionally, in accordance with OCTA's Policy, an employee who has been placed on a leave of absence or suspension for a positive result of a non-DOT test and who has successfully complied with the above paragraph must also execute a Behavioral Contract Attachment C before he/she may return to duty. This Contract allows Management to administer unannounced drug and/or alcohol tests to the employee for up to (5) years after the employee returns to duty. Follow-up testing under the Behavioral Contract applies only to non-DOT types of testing and is in addition to the DOT required random testing of safety-sensitive employees and/or SAP recommended follow-up testing.

5.5E NON-DOT FIT FOR DUTY

A fit for duty medical examination including an alcohol/drug test may be required to ensure a recovered ill or injured employee is fit to return to his/her normal job duties or to continue in his/her normal job duties.

5.5F DOT RANDOM

Only those employees who perform, or whose job description includes the performance of, safety-sensitive functions will be subject to random, unannounced testing in accordance with FTA regulations. Safety-sensitive employee selections are made using a computer-based random number selection method. Random testing shall include both a drug screen and an alcohol test. Each such employee shall have an equal chance at selection and shall remain in the pool even after being tested. Random testing will be administered at random times during OCTA's operating hours to avoid predictability. Random alcohol testing is only permissible just before an employee performs safety- sensitive duties, during that performance, and just after an employee has performed safety- sensitive duties. Each covered employee who is notified of selection for random drug or random alcohol testing must proceed to the test site immediately.

5.6 Non-DOT BIENNIAL

Employees who perform, or whose job description includes the performance of, safety-sensitive functions will be subject to biennial drug and alcohol testing.

5.7 EMPLOYEE REQUESTED TESTING

After notification by the MRO of a confirmed or verified positive drug test result, **an employee** may request that an additional test be conducted at a different Department of Health and Human Services (DHHS)-certified laboratory specified by OCTA. The test shall be conducted on the split sample that was provided at the same time as the original or primary sample. **The employee's** request must be made to the MRO within seventy-two (72) hours of notice of the primary test results.

If the result of the second test is positive, the employee shall be required to reimburse OCTA for the cost of the test.

5.8 DILUTE TESTS

If the MRO informs the Authority of a positive dilute test, the test will be considered a verified positive test.

If the MRO informs the Authority of a negative dilute test, with the creatinine between 2-5 mg/dl, then the employee must retest. The second collection must be directly observed. The test must be done immediately after notification from the MRO, with no advance notice provided. The second test result is final.

If the MRO informs the Authority of a negative dilute test with the creatinine above 5 mg/dl, then the employee will be directed to take a second test which is NOT directly observed. The result of the second test is the test of record.

Employee's refusal to retest shall be treated as a *Test Refusal.*

All employees will be treated the same for the purpose of processing dilute tests.

DRUG AND ALCOHOL POLICY MANUAL

TESTING—SECTION 5

Violations of Policy
Section 6

DRUG AND ALCOHOL POLICY MANUAL

VIOLATIONS OF POLICY—SECTION 6

6.1 DISCIPLINARY ACTION FOR VIOLATIONS OF POLICY

Under FTA guidelines, discipline for policy violations shall be determined by the employer. In general, violation of any portion of this Policy will result in disciplinary action up to and including termination of employment, even for the first offense. This section describes the consequences for violations of this Policy.

6.1A ALCOHOL POSITIVE TEST

Any employee in a safety-sensitive position whose test results are positive for alcohol may be terminated. **If the initial test indicates an alcohol concentration of 0.001 to .02, a second non-DOT alcohol test will be performed to confirm the results of the initial test. The confirmation test will be conducted after a waiting period of at least 15 minutes, but not more than 30 minutes, after completion of the initial test. A confirmed alcohol concentration greater than 0.000 will be considered a positive test and a violation of this Policy.**

Positive alcohol test results for any employee not in a safety-sensitive position will be reviewed on a case-by-case basis to determine the appropriate level of discipline, which may include discharge.

6.1B ILLEGAL DRUG POSITIVE TEST

Any employee whose test results are positive for illegal drugs is subject to employment termination.

6.1C LEGAL DRUG POSITIVE TEST

As a part of OCTA policy, it is mandatory for an employee in a safety-sensitive position to submit a completed Attachment B form for any legal drug taken, which may cause drowsiness or which may otherwise impair, to any extent, the employee's ability to safely and efficiently perform his/her job. If the Attachment B form for the legal drug has not been submitted, an employee will be suspended without pay pending the receipt and review of the Attachment B form. Additionally, the safety- sensitive employee who has failed to submit the Attachment B form will receive a disciplinary Final Warning. In instances when the employee fails to timely submit the Attachment B form, the employee's employment will be subject to termination.

6.2 FAILURE TO PASS

6.2A PRE-EMPLOYMENT (POST-OFFER) DRUG AND/OR ALCOHOL TEST

An applicant for a safety-sensitive position whose test results are positive for any illegal drug **or alcohol** will not be hired and will be given a SAP referral by the Human Resources Department. If the applicant does not pass a drug **or an alcohol test, he/she must wait twelve (12) months before reapplying** and then must present evidence of completion of a drug and/or alcohol Substance Abuse Program, from a SAP acceptable to the Authority, before he/she is eligible for employment consideration.

6.2B PRE-TRANSFER, REASONABLE SUSPICION, PROBABLE CAUSE, POST-ACCIDENT, FOLLOW-UP, FIT FOR DUTY, RETURN-TO-DUTY, OR RANDOM ALCOHOL AND/OR DRUG TEST

An employee who has a positive drug or alcohol test shall be immediately removed from duty. **Employees** who have violated a DOT drug and alcohol regulation will be referred to a SAP by Labor and Employee Relations for evaluation and recommendations concerning education, treatment, follow-up testing, and aftercare.

An employee who applies for a transfer or promotion into a safety-sensitive position who fails a drug and alcohol test shall not be transferred or promoted into a safety-sensitive position.

6.3 FAILURE OR REFUSAL TO TEST (PART 40.261)

An employee's refusal to comply with a request or directive for testing under this Policy will be considered a positive test and is grounds for employment termination. The following behaviors constitute a test refusal:

- Failure to appear for any test (except for pre-employment) within a reasonable time. **Reasonable time means that employees are required to proceed to the clinic test site immediately upon notice of selection for a drug and/or alcohol test.**
- Failure to remain at the testing site until the testing process is complete;
- Failure to provide a urine specimen for any required drug test, or fail to provide an adequate amount of breath for any required alcohol test, and the physician has determined, through a required medical evaluation, that there was no adequate medical explanation for the failure;

- Failure to permit the observation or monitoring of the specimen collection when required to do so;
- Failure to provide a sufficient amount of urine when directed, and there is no adequate medical explanation for the failure;
- Failure to take a second test when directed to do so by the employer or collector;
- Failure to undergo a medical examination when directed to do so by the MRO or employer;
- Failure to sign the certification at Step 2 of the Alcohol Testing Form;
- Failure 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, failure to wash hands after being directed to do so by the collector);
- Failure to follow the observer's instructions during an observed collection including 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;
- Possess or wear a prosthetic or other device that could be used to interfere with the collection process; and
- Admit to the collector or MRO that you adulterated or substituted the specimen.
- The MRO reports that **an employee** has a verified adulterated or substituted test result.

6.3A SHY BLADDER (PART 40.193, 40.195) SHY LUNG (PART 40.263, 40.265)

Any employee who does not provide a sufficient amount of breath to permit a valid breath test, must make a second attempt to provide a sufficient amount of breath. If the employee refuses to make the attempt, this will be considered a test refusal. If **the employee** is unable to provide the required volume of breath to permit a valid breath test, OCTA will refer **the employee** to a physician of our choice for a medical examination within 5 days to determine if there is a valid medical condition which precludes **the employee** from providing a sufficient amount of breath. If the physician finds that 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, **the employee** will be considered to have refused the test and will be subject to employment termination.

Any employee who is unable to provide the required urine sample for drug testing within three (3) hours of the first attempt, the collection process will be discontinued and the DER notified. After consulting with the MRO, the employer will direct the employee to obtain a medical evaluation from a licensed physician who is acceptable to the MRO. The medical examination must be obtained within five (5) business days of the initial collection effort. If no evidence of health problems exists, the MRO will determine that the employee refused the test and will be subject to employment termination.

Programs
Section 7

DRUG AND ALCOHOL POLICY MANUAL

PROGRAMS—SECTION 7

7.1 EMPLOYEE ASSISTANCE PROGRAM

The Authority maintains an Employee Assistance Program (EAP), which offers confidential, professional counseling to employees **and family members**. The EAP provides trained Substance Abuse Professionals (SAPs) to assist employees in dealing with drug and/or alcohol related problems before such problems impact on-job performance. Employees experiencing personal or work performance problems associated with drug or alcohol use are urged to utilize the EAP.

It is the responsibility of employees to seek assistance from the EAP *before* drug and/or alcohol problems lead to disciplinary action, which can include discharge for a first offense. Enrollment and participation in the EAP will not be used as the basis for disciplinary action and will not be used against the employee in any disciplinary proceeding. However, **if an employee violates this Policy, his/her subsequent use of the EAP on a voluntary basis will have no bearing on the determination of disciplinary action, up to and including discharge.**

In addition to employees utilizing the EAP on a voluntary basis, the EAP may also be utilized when Management refers an employee for any problems/behaviors that may be impacting job performance.

Provisions for leaves of absence for employees with drug and/or alcohol related problems who have not been found in violation of the Policy and who voluntarily seek assistance through the EAP will be considered on an individual basis.

Any employee who tests positive for the presence of alcohol or drugs at or above the DOT-established cut off levels shall be referred by Labor and Employee Relations to OCTA's EAP for an evaluation by a SAP for DOT-required tests, or **an evaluation by a Substance Abuse Counselor for non-DOT required tests.** The SAP or **Substance Abuse Counselor** will recommend education and/or treatment to the employee.

The cost of any treatment or rehabilitation services shall be paid directly by the employee or his/her insurance provider.

7.2 DRUG-FREE AWARENESS PROGRAM

To assist **employees** to understand and to avoid the perils of drug and alcohol abuse, the Authority has developed and implemented a comprehensive Drug-Free Awareness Program. The Drug-Free Awareness Program includes an ongoing educational and training

effort to prevent and eliminate drug and alcohol abuse that may affect the workplace.

The Drug-Free Awareness Program also includes the Drug-Free Workplace Act Certification For A Public Or Private Entity Attachment D and the informational material to inform employees and their families about (1) the dangers of drug and alcohol abuse in the workplace; (2) the consequences of drug and/or alcohol use on personal health, safety, and the work environment; (3) the manifestation and behavioral cues that may indicate drug and/or alcohol use and abuse; (4) educate the employees about their responsibility regarding use of prescription and OTC medication (5) the Authority's Drug and Alcohol Policy Manual; (6) the availability of treatment and counseling for employees who voluntarily seek assistance for alcohol misuse and/or drug abuse, including information about the EAP and community service hotline telephone numbers; and (7) the sanctions the Authority will impose for violations of its Drug and Alcohol Policy Manual.

As required by FTA regulations, OCTA will provide a minimum of 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.

Supervisors and/or other company officers authorized by OCTA 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. Periodic retraining will also be required of supervisory personnel.

Glossary of Terms
Section 8

DRUG AND ALCOHOL POLICY MANUAL

GLOSSARY OF TERMS—SECTION 8

ADULTERATED SPECIMEN:

A specimen is considered adulterated if it contains a substance that is not a normal constituent or contains a substance that is normally present in the body at a concentration that is not a normal physiological concentration.

ALCOHOL MISUSE:

Occurs when an employee arrives at the work site with alcohol in his/her system or the odor of alcohol on his/her breath; consumes a beverage containing alcohol while on duty or subject to duty; or during coffee or lunch breaks; or is late to work or absent from work due to the consumption of alcohol.

ATTACHMENT B FORM:

The Disclosure of Prescription and Over-the-Counter Medications form; a sample of this form is provided in Attachment B of this Policy and can be obtained from a Manager, a Supervisor, the Health, Safety, and Environmental Compliance Department, or the OCTA Intranet. Employees in safety- sensitive positions are required, under OCTA Policy, to file a completed Attachment B form.

BREATH ALCOHOL TECHNICIAN (BAT):

The Breath Alcohol Technician instructs and assists employees in the alcohol testing process; operates an evidential breath testing device.

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 SITES:

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

DRUG & ALCOHOL MANAGER (DAPM):

An employee authorized by OCTA to manage and monitor the Drug and Alcohol testing program.

DESIGNATED EMPLOYER REPRESENTATIVE (DER):

Designated Employer Representative is 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.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES (DHHS OR HHS):

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

DHHS CERTIFIED LABS:

Any U.S. laboratory certified by DHHS under the National Laboratory Certification Program as meeting the minimum standards of Subpart C of the DHHS Mandatory Guidelines for Federal Workplace Drug Testing Programs.

DILUTED SPECIMEN:

Diluted specimens have creatinine and specific gravity values that are lower than expected for human urine. A dilute test will be reported as a positive or negative. For a positive dilute test, the Authority treats the result as a positive test and removes the employee from safety-sensitive duty. For a negative dilute test (See Section 5.7), the Authority will require, as a matter of policy, employees to retest. The second test is the test of record, even if the second test is also a negative dilute.

U.S. DEPARTMENT OF TRANSPORTATION (DOT):

The U.S. Department of Transportation is a government entity which oversees several agencies, including the Federal Transit Administration (FTA) or any designee of a DOT agency.

EVIDENTIAL BREATH TESTING (EBT) DEVICE:

A device approved by the National Highway Traffic Safety Administration (NHTSA) for the evidential breath testing and placed on NHTSA's "Conforming Products List of Evidential Breath Measurements Devices," and conforming with the model specifications available from NHTSA Traffic Safety Program.

FEDERAL TRANSIT ADMINISTRATION (FTA):

The Federal Transit Administration, an agency of the U.S. Department of Transportation.

INVALID SPECIMEN:

An invalid specimen is one that contains 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.

ILLEGAL DRUG:

Any drug which (a) is not legally obtainable or (b) is legally obtainable but had not been legally obtained or is not being used for its prescribed purposes. It includes prescribed drugs not legally obtained and prescribed drugs not being used for prescribed purposes.

LEGAL DRUG:

Any drug prescribed by a physician for the employee or any over-the-counter drug which has been legally obtained which is being used for the purpose for which it has been prescribed or manufactured. A drug, which is legally obtainable but is not being used for its prescribed purposes, is an illegal drug, not a legal drug, under this Policy.

MEDICAL REVIEW OFFICER ("MRO"):

A person who is a licensed physician, with MRO certification, who is appointed and authorized by the Authority to be responsible for receiving and reviewing laboratory results generated by OCTA's drug testing program and for evaluating medical explanations for certain drug test results. The MRO shall report each verified positive test result to the DER in the **Health, Safety, and Environmental Compliance** Department. The MRO will also determine (when the Authority requests such a determination) whether an employee who is taking a legal drug(s) may work while under the influence of such drug(s).

NHTSA:

National Highway Traffic Safety Administration.

NON-SAFETY SENSITIVE POSITION:

Any position which does *not* entail any duty related to the safe operation of the Authority's mass transportation service.

POSITIVE ALCOHOL TEST:

Under the Authority's Drug and Alcohol Policy Manual, the presence of alcohol in a body at a concentration **greater than 0.000** as measured by an Evidential Breath Testing (EBT) Device.

POSITIVE DRUG TEST:

Any urine that is chemically tested (screened and confirmed) which shows the presence of controlled substances, as defined by DOT standards, and is verified by the MRO.

PRE-EMPLOYMENT TESTING:

Employees that are either applying for or transferring to a safety-sensitive position or if ninety (90) days have elapsed since the employee performed safety-sensitive duties and the individual was not in the random pool.

PROBABLE CAUSE:

The Authority will require a drug and/or an alcohol test on any employee who is reasonably suspected of violating this policy, including but not limited to, any employee suspected of possessing, using or being under the influence of alcohol or an illegal drug, a legal drug if such use would violate this policy, while on duty or in Authority vehicles or on Authority property or in Authority uniform.

REASONABLE SUSPICION:

The Federal Transit Administration (FTA) regulations require a safety-sensitive employee to submit a test when the employer has reasonable suspicion that the employee has used a prohibited drug or has misused alcohol. The request to undergo a reasonable suspicion test must be based on specific, contemporaneous, articulable observations concerning the appearance, behavior, speech or body odor of the safety-sensitive employee.

SAFETY-SENSITIVE POSITION:

Any position which entails any duty related to the safe operation of the Authority's mass transportation service, including: (a) operation of a revenue service vehicle, whether or not such vehicle is in revenue service; (b) operation of a non-revenue service vehicle that requires a CDL (c) controlling dispatch or movement of a revenue service vehicle or equipment used in revenue service; (d) maintaining revenue service of vehicles or equipment used in revenue service; (e) carrying a firearm for security purposes; and (f) supervising an employee who performs a function in (a)-(e) above and performing or called upon to perform a safety sensitive function. Positions currently classified as safety-sensitive positions are listed in Attachment A of this Policy and are subject to revision as needed.

SCREENING TEST TECHNICIAN (STT):

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

SUBSTANCE ABUSE PROFESSIONAL (SAP):

An OCTA authorized licensed physician or a licensed or certified psychologist, social worker, employee assistance professional, or a certified addiction counselor, with knowledge of and clinical experience in the diagnosis and treatment of drug and related disorders; evaluates employees who have violated a DOT drug and alcohol regulation and makes recommendations concerning education, treatment, follow-up testing, and aftercare. Although in most cases, an employee will be terminated for violation of this Policy; in cases in which an employee is suspended or placed on a leave of absence, OCTA will determine when/or if the employee may return to duty.

SUBSTITUED SPECIMEN:

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

UNDER THE INFLUENCE:

When an employee is affected to any extent by alcohol or a drug, or metabolites of such, or the combination of alcohol and a drug, or has alcohol or a drug, or metabolites, of such, in the employee’s body in any detectable amount.

END OF POLICY

DRUG AND ALCOHOL POLICY MANUAL

GLOSSARY OF TERMS—SECTION 8

Attachments
Section 9

DRUG AND ALCOHOL POLICY MANUAL

ATTACHMENTS—SECTION 9

ATTACHMENT A

SAFETY-SENSITIVE POSITIONS

Any level of job classification or within the general job classification of the positions listed below are considered safety-sensitive. The listing is subject to revision and may not be all inclusive due to changes in job position titles.

- Coach Operator
- Electronic Technician
- Maintenance Field Administrator
- Field Supervisor
- Instructor (Maintenance, Coach Operations)
- Mechanic
- Automotive Mechanic
- Machinist
- Radio Dispatcher
- Service Worker
- Supervisor, Maintenance
- Section Supervisor/Section Manager:
    - Central Communications
    - Field Operations
    - Bus Operations
    - Instruction
    - Vehicle Maintenance
- Window Dispatcher
- Or any other employee who operates a revenue service vehicle (whether or not the vehicle is in revenue service), dispatch (anyone who controls revenue service vehicles' movement), maintenance of a revenue service vehicle or equipment used in revenue service, security personnel who carry firearms, and any other employee who through course of employment is required to hold a Commercial Driver's License (CDL).

DRUG AND ALCOHOL POLICY MANUAL

ATTACHMENTS—SECTION 9

OCTA

ATTACHMENT B

Disclosure of Prescription and Over-the-Counter Drugs

PRESCRIPTION DRUGS – PHYSICIAN SIGNATURE REQUIRED

Instructions For Employees In Safety-Sensitive Positions

Attachment B forms are required by Orange County Transportation Authority (OCTA) for employees in Safety- Sensitive Positions.

1. If you are disclosing the use of a new prescription drug, have your doctor complete "Physician" section in full with signature, attach a complete* copy of your prescription label, complete "Employee" section on this form and forward the form and attachment directly to the Health, Safety, and Environmental Compliance Department in the confidential envelope provided at each base.
2. If you are disclosing a prescription drug renewal, complete "Employee" section of this form, attach a copy of your prescription renewal label, and forward directly to the Health, Safety, and Environmental Compliance Department in the confidential envelope provided at each base.
3. Indicate in "Employee" section whether prescription is new or a refill.

* Complete – includes date of prescription, name of medication, dosage, directions for use, physician's name, and expiration date.

TO BE COMPLETED BY PHYSICIAN

Includes only those legal drugs which may cause drowsiness or impair employee's ability to safely perform his/her job duties (attached), drugs listed on Schedule I (attached), amphetamines, narcotics, or other habit forming drugs.

I, _____ (Physician's Name) am aware of the job duties of _____ (Employee's Name), who is a _____ (Employee's Position/Job Title) at Orange County Transportation Authority. I have prescribed for such employee the medication described below on _____ (Date).

(Please print the following information legibly):

Name of Medication: _____

Dosage: _____

Duration To Be Taken: _____

I am familiar with the employee's medical history and assigned job duties and have advised the employee that the prescribed substance, legal drug and/or over the counter medication will not adversely affect the employee's ability to safely operate a commercial motor vehicle or machinery or to perform his/her job competently and safely.

_____ Physician's Signature

_____ Physician's Telephone Number

_____ Physician's Printed Name and Address Stamp

_____ Date

TO BE COMPLETED BY EMPLOYEE

I understand that, in accordance with the OCTA Alcohol and Drug Policy, it is my obligation to inform OCTA's Health Safety and Environmental Compliance Department of any legal drug or prescription medication I intend to take that may cause drowsiness or impair my ability to safely perform my job duties, drugs listed on Schedule I (attached), amphetamines, narcotics, or other habit forming drugs.

Additionally, I understand that on-going or periodic use of prescription drugs requires a fully completed and appropriately signed Attachment B form, which must be submitted at any time I start, or renew taking a legal prescription drug. I acknowledge that I will read the labels on all medications that I intend to take and that I will take such medication according to label directions.

Please check one: New Prescription ☐ OR ☐ Refill Prescription

_____ Employee's Signature

_____ Employee's Work Location and Supervisor

_____ Employee's Printed Name

_____ Employee's Badge #

_____ **Date**

OCTA

ATTACHMENT B

Disclosure of Prescription and Over-the-Counter Drugs

OVER-THE-COUNTER MEDICATION

Instructions For Employees In Safety-Sensitive Positions

1. Attachment B forms are required by Orange County Transportation Authority (OCTA) for employees in Safety-Sensitive positions
2. If you are disclosing the use of over-the-counter medications, complete this page and sign the "Employee" section below.

TO BE COMPLETED BY EMPLOYEE

Include only those over-the-counter medications which may cause drowsiness or impair employee's ability to safely perform his/her job duties (attached), drugs listed on Schedule I (attached), amphetamines, narcotics, or other habit forming drugs.

I, _____ , am a Safety Sensitive employee. My job title is
Print/Type Name Legibly

_____ , and my work location is _____ .
Print/Type Job Title Print/Type Work Location

☐ **I take the following over-the-counter medications as directed* on the package.**

* If the medication is not taken as directed, please explain: _____

_____

GENERAL PAIN RELIEF	COLD/FLU MEDICATION
SINUS RELIEF	**VITAMINS/MINERALS/HERBS**
OTHER	**OTHER**

I understand that, in accordance with OCTA's Drug and Alcohol Policy and the purpose of review and determination of my eligibility to work, it is my obligation to inform OCTA of any over-the-counter medication I intend to take that may cause drowsiness or impair my ability to safely perform my job duties or ability to operate machinery or a commercial motor vehicle. I understand that I may not engage in any safety-sensitive functions while taking any legal OTC drug that contains a warning label on the packaging which indicates that the drug may cause drowsiness or otherwise impair my ability to safely perform the job duties.

Additionally, I understand that on-going or periodic use of these over-the-counter medications, requires a fully completed and appropriately signed Attachment B form. I acknowledge that I read the labels on all medications that I intend to take and that I will take such medication according to label directions.

_____ _____ _____
Employee's Signature Employee's Badge # Date

FOR OCTA USE ONLY

Date HSEC Received: _____ **Received By:** _____

HSEC: ☐ Reviewed ☐ MRO Contacted ☐ Supervisor
Notified:

_____

Date: _____ **Time:** _____

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ATTACHMENT B

Disclosure of Prescription and Over-the-Counter Drugs

SCHEDULE I

[Code of Federal Regulations]
[Title 21, Volume 9]
[Revised as of April 1, 2015]
[CITE: 21CFR1308.11]

TITLE 21--FOOD AND DRUGS
CHAPTER II--DRUG ENFORCEMENT ADMINISTRATION
DEPARTMENT OF JUSTICE

PART 1308 -- SCHEDULES OF CONTROLLED SUBSTANCES

Schedules

Sec. 1308.11 Schedule I.

(a) Schedule I shall consist of the drugs and other substances, by whatever official name, common or usual name, chemical name, or brand name designated, listed in this section. Each drug or substance has been assigned the DEA Controlled Substances Code Number set forth opposite it.

(b) *Opiates.* Unless specifically excepted or unless listed in another schedule, any of the following opiates, including their isomers, esters, ethers, salts, and salts of isomers, esters and ethers, whenever the existence of such isomers, esters, ethers and salts is possible within the specific chemical de signation (for purposes of paragraph (b)(34) only, the term isomer includes the optical and geometric isomers):

(1) Acetyl-alpha-methylfentanyl (N-[1-(1-methyl-2-phenethyl)-4-piperidinyl]-N-phenylacetamide)	9815
(2) Acetylmethadol	9601
(3) Allylprodine	9602
(4) Alphacetylmethadol (except levo-alphacetylmethadol also known as levo-alpha-acetylmethadol, levomethadyl acetate, or LAAM)	9603
(5) Alphameprodine	9604
(6) Alphamethadol	9605
(7) Alpha-methylfentanyl (N-[1-(alpha-methyl-beta-phenyl)ethyl-4-piperidyl] propionanilide; 1-(1-methyl-2-phenylethyl)-4-(N-propanilido) piperidine)	9814
(8) Alpha-methylthiofentanyl (N-[1-methyl-2-(2-thienyl)ethyl-4-piperidinyl]-N-phenylpropanamide)	9832
(9) Benzethidine	9606
(10) Betacetylmethadol	9607
(11) Beta-hydroxyfentanyl (N-[1-(2-hydroxy-2-phenethyl)-4-piperidinyl]-N-phenylpropanamide)	9830
(12) Beta-hydroxy-3-methylfentanyl (other name: N-[1-(2-hydroxy-2-phenethyl)-3-methyl-4-piperidinyl]-N-phenylpropanamide	9831
(13) Betameprodine	9608
(14) Betamethadol	9609
(15) Betaprodine	9611
(16) Clonitazene	9612
(17) Dextromoramide	9613
(18) Diampromide	9615

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Disclosure of Prescription and Over-the-Counter Drugs

(19) Diethylthiambutene	9616
(20) Difenoxin	9168
(21) Dimenoxadol	9617
(22) Dimepheptanol	9618
(23) Dimethylthiambutene	9619
(24) Dioxaphetyl butyrate	9621
(25) Dipipanone	9622
(26) Ethylmethylthiambutene	9623
(27) Etonitazene	9624
(28) Etoxeridine	9625
(29) Furethidine	9626
(30) Hydroxypethidine	9627
(31) Ketobemidone	9628
(32) Levomoramide	9629
(33) Levophenacylmorphan	9631
(34) 3-Methylfentanyl (N-[3-methyl-1-(2-phenylethyl)-4-piperidyl]-N-phenylpropanamide)	9813
(35) 3-methylthiofentanyl (N-[(3-methyl-1-(2-thienyl)ethyl-4-piperidinyl]-N-phenylpropanamide)	9833
(36) Morpheridine	9632
(37) MPPP (1-methyl-4-phenyl-4-propionoxypiperidine)	9661
(38) Noracymethadol	9633
(39) Norlevorphanol	9634
(40) Normethadone	9635
(41) Norpipanone	9636
(42) Para-fluorofentanyl (N-(4-fluorophenyl)-N-[1-(2-phenethyl)-4-piperidinyl] propanamide	9812
(43) PEPAP (1-(-2-phenethyl)-4-phenyl-4-acetoxypiperidine	9663
(44) Phenadoxone	9637
(45) Phenampromide	9638
(46) Phenomorphan	9647
(47) Phenoperidine	9641
(48) Piritramide	9642
(49) Proheptazine	9643
(50) Properidine	9644
(51) Propiram	9649
(52) Racemoramide	9645
(53) Thiofentanyl (N-phenyl-N-[1-(2-thienyl)ethyl-4-piperidinyl]-propanamide	9835
(54) Tilidine	9750
(55) Trimeperidine	9646

(c) *Opium derivatives.* Unless specifically excepted or unless listed in another schedule, any of the following opium derivatives, its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

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Disclosure of Prescription and Over-the-Counter Drugs

(1) Acetorphine	9319
(2) Acetyldihydrocodeine	9051
(3) Benzylmorphine	9052
(4) Codeine methylbromide	9070
(5) Codeine-N-Oxide	9053
(6) Cyprenorphine	9054
(7) Desomorphine	9055
(8) Dihydromorphine	9145
(9) Drotebanol	9335
(10) Etorphine (except hydrochloride salt)	9056
(11) Heroin	9200
(12) Hydromorphinol	9301
(13) Methyldesorphine	9302
(14) Methyldihydromorphine	9304
(15) Morphine methylbromide	9305
(16) Morphine methylsulfonate	9306
(17) Morphine-N-Oxide	9307
(18) Myrophine	9308
(19) Nicocodeine	9309
(20) Nicomorphine	9312
(21) Normorphine	9313
(22) Pholcodine	9314
(23) Thebacon	9315

(d) *Hallucinogenic substances.* Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation, which contains any quantity of the following hallucinogenic substances, or which contains any of its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation (for purposes of this paragraph only, the term "isomer" includes the optical, position and geometric isomers):

(1) Alpha-ethyltryptamine	7249
Some trade or other names: etryptamine; Monase; [alpha]-ethyl-1H-indole-3-ethanamine; 3-(2-aminobutyl) indole; [alpha]-ET; and AET.	
(2) 4-bromo-2,5-dimethoxy-amphetamine	7391
Some trade or other names: 4-bromo-2,5-dimethoxy-[alpha]-methylphenethylamine; 4-bromo-2,5-DMA	
(3) 4-Bromo-2,5-dimethoxyphenethylamine	7392
Some trade or other names: 2-(4-bromo-2,5-dimethoxyphenyl)-1-aminoethane; alpha-desmethyl DOB; 2C-B, Nexus.	
(4) 2,5-dimethoxyamphetamine	7396
Some trade or other names: 2,5-dimethoxy-[alpha]-methylphenethylamine; 2,5-DMA	
(5) 2,5-dimethoxy-4-ethylamphet-amine	7399
Some trade or other names: DOET	
(6) 2,5-dimethoxy-4-(n)-propylthiophenethylamine (other name: 2C-T-7)	7348

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(7) 4-methoxyamphetamine	7411
Some trade or other names: 4-methoxy-[alpha]-methylphenethylamine; paramethoxyamphetamine, PMA	
(8) 5-methoxy-3,4-methylenedioxy-amphetamine	7401
(9) 4-methyl-2,5-dimethoxy-amphetamine	7395
Some trade and other names: 4-methyl-2,5-dimethoxy-[alpha]-methylphenethylamine; "DOM"; and "STP"	
(10) 3,4-methylenedioxy amphetamine	7400
(11) 3,4-methylenedioxymethamphetamine (MDMA)	7405
(12) 3,4-methylenedioxy-N-ethylamphetamine (also known as N-ethyl-alpha-methyl-3,4(methylenedioxy)-phenethylamine, N-ethyl MDA, MDE, MDEA	7404
(13) N-hydroxy-3,4-methylenedioxyamphetamine (also known as N-hydroxy-alpha-methyl-3,4(methylenedioxy)-phenethylamine, and N-hydroxy MDA	7402
(14) 3,4,5-trimethoxy amphetamine	7390
(15) 5-methoxy-N,N-dimethyltryptamine Some trade or other names: 5-methoxy-3-[2-(dimethylamino)ethyl]indole; 5-MeO-DMT	7431
(16) Alpha-methyltryptamine (other name: AMT)	7432
(17) Bufotenine	7433
Some trade and other names: 3-([beta]-Dimethylaminoethyl)-5-hydroxyindole; 3-(2-dimethylaminoethyl)-5-indolol; N, N-dimethylserotonin; 5-hydroxy-N,N-dimethyltryptamine; mappine	
(18) Diethyltryptamine	7434
Some trade and other names: N,N-Diethyltryptamine; DET	
(19) Dimethyltryptamine	7435
Some trade or other names: DMT	
(20) 5-methoxy-N,N-diisopropyltryptamine (other name: 5-MeO-DIPT)	7439
(21) Ibogaine	7260
Some trade and other names: 7-Ethyl-6,6[beta],7,8,9,10,12,13-octahydro-2-methoxy-6,9-methano-5H-pyrido [1', 2':1,2] azepino [5,4-b] indole; Tabernanthe iboga	
(22) Lysergic acid diethylamide	7315
(23) Marihuana	7360
(24) Mescaline	7381
(25) Parahexyl--7374; some trade or other names: 3-Hexyl-1-hydroxy-7,8,9,10-tetrahydro-6,6,9-trimethyl-6H-dibenzo[b,d]pyran; Synhexyl.	
(26) Peyote	7415
Meaning all parts of the plant presently classified botanically as Lophophora williamsii Lemaire, whether growing or not, the seeds thereof, any extract from any part of such plant, and every compound, manufacture, salts, derivative, mixture, or preparation of such plant, its seeds or extracts	
(Interprets 21 USC 812(c), Schedule I(c) (12))	
(27) N-ethyl-3-piperidyl benzilate	7482
(28) N-methyl-3-piperidyl benzilate	7484
(29) Psilocybin	7437
(30) Psilocyn	7438
(31) Tetrahydrocannabinols	7370
Meaning tetrahydrocannabinols naturally contained in a plant of the genus Cannabis (cannabis plant), as well as synthetic equivalents of the substances contained in the cannabis plant, or in the resinous	

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Disclosure of Prescription and Over-the-Counter Drugs

extractives of such plant, and/or synthetic substances, derivatives, and their isomers with similar chemical structure and pharmacological activity to those substances contained in the plant, such as the following:	
1 cis or trans tetrahydrocannabinol, and their optical isomers	
6 cis or trans tetrahydrocannabinol, and their optical isomers	
3, 4 cis or trans tetrahydrocannabinol, and its optical isomers	
(Since nomenclature of these substances is not internationally standardized, compounds of these structures, regardless of numerical designation of atomic positions covered.)	
(32) Ethylamine analog of phencyclidine	7455
Some trade or other names: N-ethyl-1-phenylcyclohexylamine, (1-phenylcyclohexyl)ethylamine, N-(1-phenylcyclohexyl)ethylamine, cyclohexamine, PCE	
(33) Pyrrolidine analog of phencyclidine	7458
Some trade or other names: 1-(1-phenylcyclohexyl)-pyrrolidine, PCPy, PHP	
(34) Thiophene analog of phencyclidine	7470
Some trade or other names: 1-[1-(2-thienyl)-cyclohexyl]-piperidine, 2-thienylanalog of phencyclidine, TPCP, TCP	
(35) 1-[1-(2-thienyl)cyclohexyl]pyrrolidine	7473
Some other names: TCPy	
(36) 4-methylmethcathinone (Mephedrone)	1248
(37) 3,4-methylenedioxypyrovalerone (MDPV)	7535
(38) 2-(2,5-Dimethoxy-4-ethylphenyl)ethanamine (2C-E)	7509
(39) 2-(2,5-Dimethoxy-4-methylphenyl)ethanamine (2C-D)	7508
(40) 2-(4-Chloro-2,5-dimethoxyphenyl)ethanamine (2C-C)	7519
(41) 2-(4-Iodo-2,5-dimethoxyphenyl)ethanamine (2C-I)	7518
(42) 2-[4-(Ethylthio)-2,5-dimethoxyphenyl]ethanamine (2C-T-2)	7385
(43) 2-[4-(Isopropylthio)-2,5-dimethoxyphenyl]ethanamine (2C-T-4)	7532
(44) 2-(2,5-Dimethoxyphenyl)ethanamine (2C-H)	7517
(45) 2-(2,5-Dimethoxy-4-nitro-phenyl)ethanamine (2C-N)	7521
(46) 2-(2,5-Dimethoxy-4-(n)-propylphenyl)ethanamine (2C-P)	7524
(47) 3,4-Methylenedioxy-N-methylcathinone (Methylone)	7540

(e) *Depressants.* Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) gamma-hydroxybutyric acid (some other names include GHB; gamma-hydroxybutyrate; 4-hydroxybutyrate; 4-hydroxybutanoic acid; sodium oxybate; sodium oxybutyrate)	2010
(2) Mecloqualone	2572
(3) Methaqualone	2565

(f) *Stimulants.* Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers, and salts of isomers:

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(1) Aminorex (Some other names: aminoxaphen; 2-amino-5-phenyl-2-oxazoline; or 4,5-dihydro-5-phenly-2-oxazolamine)	1585
(2) N-Benzylpiperazine (some other names: BZP, 1-benzylpiperazine)	7493
(3) Cathinone	1235
Some trade or other names: 2-amino-1-phenyl-1-propanone, alpha-aminopropiophenone, 2-aminopropiophenone, and norephedrone	
(4) Fenethylline	1503
(5) Methcathinone (Some other names: 2-(methylamino)-propiophenone; alpha-(methylamino)propiophenone; 2-(methylamino)-1-phenylpropan-1-one; alpha-N-methylaminopropiophenone; monomethylpropion; ephedrone; N-methylcathinone; methylcathinone; AL-464; AL-422; AL-463 and UR1432), its salts, optical isomers and salts of optical isomers	1237
(6) (+/-)cis-4-methylaminorex ((+/-)cis-4,5-dihydro-4-methyl-5-phenyl-2-oxazolamine)	1590
(7) N-ethylamphetamine	1475
(8) N,N-dimethylamphetamine (also known as N,N-alpha-trimethyl-benzeneethanamine; N,N-alpha-trimethylphenethylamine)	1480

(g) *Cannabimimetic agents.* Unless specifically exempted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances, or which contains their salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) 5-(1,1-dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (CP-47,497)	7297
(2) 5-(1,1-dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (cannabicyclohexanol or CP-47,497 C8-homolog)	7298
(3) 1-pentyl-3-(1-naphthoyl)indole (JWH-018 and AM678)	7118
(4) 1-butyl-3-(1-naphthoyl)indole (JWH-073)	7173
(5) 1-hexyl-3-(1-naphthoyl)indole (JWH-019)	7019
(6) 1-[2-(4-morpholinyl)ethyl]-3-(1-naphthoyl)indole (JWH-200)	7200
(7) 1-pentyl-3-(2-methoxyphenylacetyl)indole (JWH-250)	6250
(8) 1-pentyl-3-[1-(4-methoxynaphthoyl)]indole (JWH-081)	7081
(9) 1-pentyl-3-(4-methyl-1-naphthoyl)indole (JWH-122)	7122
(10) 1-pentyl-3-(4-chloro-1-naphthoyl)indole (JWH-398)	7398
(11) 1-(5-fluoropentyl)-3-(1-naphthoyl)indole (AM2201)	7201
(12) 1-(5-fluoropentyl)-3-(2-iodobenzoyl)indole (AM694)	7694
(13) 1-pentyl-3-[(4-methoxy)-benzoyl]indole (SR-19 and RCS-4)	7104
(14) 1-cyclohexylethyl-3-(2-methoxyphenylacetyl)indole 7008 (SR-18 and RCS-8)	7008
(15) 1-pentyl-3-(2-chlorophenylacetyl)indole (JWH-203)	7203

(h) *Temporary listing of substances subject to emergency scheduling.* Any material, compound, mixture or preparation which contains any quantity of the following substances:

(1) (1-pentyl-1*H* -indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone, its optical, positional, and geometric isomers, salts and salts of isomers--7144 (Other names: UR-144, 1-pentyl-3-(2,2,3,3-tetramethylcyclopropoyl)indole)

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(2) [1-(5-fluoro-pentyl)-1*H* -indol-3-yl](2,2,3,3-tetramethylcyclopropyl)methanone, its optical, positional, and geometric isomers, salts and salts of isomers--7011 (Other names: 5-fluoro-UR-144, 5-F-UR-144, XLR11, 1-(5-fluoro-pentyl)-3-(2,2,3,3-tetramethylcyclopropoyl)indole)

(3) *N* -(1-adamantyl)-1-pentyl-1*H* -indazole-3-carboxamide, its optical, positional, and geometric isomers, salts and salts of isomers--7048 (Other names: APINACA, AKB48)

(4) 2-(4-iodo-2,5-dimethoxyphenyl)-*N* -(2-methoxybenzyl)ethanamine, its optical, positional, and geometric isomers, salts and salts of isomers--7538 (Other names: 25I-NBOMe; 2C-I-NBOMe; 25I; Cimbi-5)

(5) 2-(4-chloro-2,5-dimethoxyphenyl)-*N* -(2-methoxybenzyl)ethanamine, its optical, positional, and geometric isomers, salts and salts of isomers--7537 (Other names: 25C-NBOMe; 2C-C-NBOMe; 25C; Cimbi-82)

(6) 2-(4-bromo-2,5-dimethoxyphenyl)-*N* -(2-methoxybenzyl)ethanamine, its optical, positional, and geometric isomers, salts and salts of isomers--7536

(Other names: 25B-NBOMe; 2C-B-NBOMe; 25B; Cimbi-36)

(7) Quinolin-8-yl 1-pentyl-1*H* -indole-3-carboxylate, its optical, positional, and geometric isomers, salts and salts of isomers--7222 (Other names: PB-22; QUPIC)

(8) Quinolin-8-yl 1-(5-fluoropentyl)-1*H* -indole-3-carboxylate, its optical, positional, and geometric isomers, salts and salts of isomers--7225 (Other names: 5-fluoro-PB-22; 5F-PB-22)

(9) *N* -(1-amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1*H* -indazole-3-carboxamide, its optical, positional, and geometric isomers, salts and salts of isomers--7012 (Other names: AB-FUBINACA)

(10) *N* -(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1*H* -indazole-3-carboxamide, its optical, positional, and geometric isomers, salts and salts of isomers--7035 (Other names: ADB-PINACA)

(11) 4-methyl-*N* -ethylcathinone, its optical, positional, and geometric isomers, salts and salts of isomers--1249 (Other names: 4-MEC; 2-(ethylamino)-1-(4-methylphenyl)propan-1-one)

(12) 4-methyl-*alpha* -pyrrolidinopropiophenone, its optical, positional, and geometric isomers, salts and salts of isomers--7498 (Other names: 4-MePPP; MePPP; 4-methyl-[alpha]-pyrrolidinopropiophenone; 1-(4-methylphenyl)-2-(pyrrolidin-1-yl)-propan-1-one)

(13) *alpha* -pyrrolidinopentiophenone, its optical, positional, and geometric isomers, salts and salts of isomers--7545 (Other names: [alpha]-PVP; [alpha]-pyrrolidinovalerophenone; 1-phenyl-2-(pyrrolidin-1-yl)pentan-1-one)

(14) Butylone, its optical, positional, and geometric isomers, salts and salts of isomers--7541 (Other names: bk-MBDB; 1-(1,3-benzodioxol-5-yl)-2-(methylamino)butan-1-one)

(15) Pentedrone, its optical, positional, and geometric isomers, salts and salts of isomers--1246 (Other names: [alpha]-methylaminovalerophenone; 2-(methylamino)-1-phenylpentan-1-one)

(16) Pentylone, its optical, positional, and geometric isomers, salts and salts of isomers--7542 (Other names: bk-MBDP; 1-(1,3-benzodioxol-5-yl)-2-(methylamino)pentan-1-one)

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(17) 4-fluoro-*N* -methylcathinone, its optical, positional, and geometric isomers, salts and salts of isomers--1238 (Other names: 4-FMC; flephedrone; 1-(4-fluorophenyl)-2-(methylamino)propan-1-one)

(18) 3-fluoro-*N* -methylcathinone, its optical, positional, and geometric isomers, salts and salts of isomers--1233 (Other names: 3-FMC; 1-(3-fluorophenyl)-2-(methylamino)propan-1-one)

(19) Naphyrone, its optical, positional, and geometric isomers, salts and salts of isomers--1258 (Other names: naphthylpyrovalerone; 1-(naphthalen-2-yl)-2-(pyrrolidin-1-yl)pentan-1-one)

(20) *alpha* -pyrrolidinobutiophenone, its optical, positional, and geometric isomers, salts and salts of isomers--7546 (Other names: [alpha]-PBP; 1-phenyl-2-(pyrrolidin-1-yl)butan-1-one)

(21) *N* -(1-amino-3-methyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1*H* -indazole-3-carboxamide, its optical, positional, and geometric isomers, salts, and salts of isomers--7031 (Other names: AB-CHMINACA).

(22) *N* -(1-amino-3-methyl-1-oxobutan-2-yl)-1-pentyl-1*H* -indazole-3-carboxamide, its optical, positional, and geometric isomers, salts, and salts of isomers--7023 (Other names: AB-PINACA).

(23) [1-(5-fluoropentyl)-1*H* -indazol-3-yl](naphthalen-1-yl)methanone, its optical, positional, and geometric isomers, salts, and salts of isomers--7024 (Other names: THJ-2201).

(24) *N* -(1-phenethylpiperidin-4-yl)-*N* -phenylacetamide, its optical, positional, and geometric isomers, salts and salts of isomers (Other names: acetyl fentanyl) (9821).

[39 FR 22141, June 20, 1974]

Editorial Note:

For Federal Register citations affecting 1308.11, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.fdsys.gov*.

The information on this page is current as of **April 1 2015**.

For the most up-to-date version of CFR Title 21, go to the Electronic Code of Federal Regulations (eCFR).[8]

OCTA

ATTACHMENT B

Disclosure of Prescription and Over-the-Counter Drugs

SUMMARY OF SAFETY SENSITIVE JOB DUTIES

Central Communications –
Under general supervision, provides management by monitoring and coordinating the delivery of a 24/7 fixed route bus service through two-way radio communications with **bus drivers**, ensures safe, reliable, courteous service. Provides customer service to both internal and external customers.

Coach Operator –
Responsible for safely operating all types of agency motor coaches/ **buses** and on-board equipment to transport passengers over specified routes. **Position requires a commercial driver's license with passenger endorsement.**

Field Supervisor –
Under general supervision and with the support of Central Communications, physically manages the 24/7 bus system to ensure safe, reliable, courteous service. Provides customer service to both internal and external customers. **Position requires a commercial driver's license with passenger endorsement.**

Line Supervisor –
Under general direction, supervises maintenance employees in the repair, maintenance, cleaning, servicing, and/or revenue transferring for the agency's fleet of buses and other vehicles.

Mechanic –
Under supervision, diagnoses and makes mechanical repairs to buses and other automotive equipment. **Position requires a commercial driver's license with passenger endorsement.**

Service Worker –
Under direct supervision, performs vehicle movement, servicing, fueling, refilling consumables, repairs and cleaning. **Position requires a commercial driver's license with passenger endorsement.**

Window Dispatcher –
Under general supervision, provides management by monitoring and coordinating the delivery of a 24/7 fixed route bus service from the base, ensuring safe, reliable, courteous service. Provides customer service to both internal and external customers.

Instructor *(Bus Operations & Maintenance)*
Bus Operations
Under minimal supervision, conducts classroom and on-the-job training for Coach Operators with a focus on customer service, safety, courtesy, and reliability. Designs, develops, and implements training programs that meet regulatory and agency guidelines. Evaluates student performance and administers discipline.

Maintenance
Under general supervision, researches, designs, coordinates, and presents training classes, which include maintenance of vehicles, use of tools and equipment, and Maintenance Certification Training. Provides consultation on technical vehicle issues.

Other –
Any employee who operates a revenue service vehicle (whether or not the vehicle is in revenue service), dispatch (anyone who controls revenue service vehicles' movement), maintenance of a revenue service vehicle or equipment used in revenue serve, security personnel who carry firearms, and any other employee who through course of employment is required to hold a Commercial Driver's License (CDL).

ATTACHMENT B

Disclosure of Prescription and Over-the-Counter Drugs

SUMMARY OF SAFETY SENSITIVE
JOB DUTIES

Other-

Any employee who operates a revenue service vehicle (whether or not the vehicle is in revenue service), dispatch (anyone who controls revenue service vehicles' movement), maintenance of a revenue service vehicle or equipment used in revenue serve, security personnel who carry firearms, and any other employee who through course of employment is required to hold a Commercial Driver's License (COL).

Page 12 of 13

ATTACHMENT C

DRUG AND ALCOHOL BEHAVORIAL CONTRACT

I understand that I will be allowed to continue my employment with Orange County Transportation Authority if I will participate in and submit continuing documentation on a monthly basis of my participation in an Authority approved substance abuse treatment program. Additionally, u p o n successful completion of said program, I will provide the necessary documentation of such.

I agree not to use illegal drugs, including marijuana and alcohol, in accordance with the Authority's Alcohol/Drug Policy.

I understand that in order to return to my employment, I must submit to additional alcohol/drug test(s) and that such test(s) demonstrate there is no trace of alcohol or a drug or metabolite of any drug in my system.

I also understand that during the sixty (60) months following my return to work I may be tested without prior notice and if there is any trace of drug or metabolites and/or alcohol in my system, my employment with Orange County Transportation Authority will be terminated. Additionally, I understand that refusal to submit to such a test will result in the termination of my employment.

I understand and agree to all the above conditions. I also understand and agree that failure to meet all terms and conditions of this commitment will result in the termination of my employment, with no Hearing Before Discharge and no right of appeal through the grievance procedure.

_____ _____
Employee Signature Date

_____ _____
Union Representative Signature Date

_____ _____
Base Manager Signature Date

_____ _____
Labor and Employee Relations Representative Signature Date

ATTACHMENT D

DRUG –FREE WORKPLACE ACT CERTIFICATION FOR A PUBLIC OR PRIVATE ENTITY

Orange County Transportation Authority (OCTA or Authority) has a vital interest in providing its employees with safe and healthful working conditions and providing its riders and the public with high quality public transportation that is effective, safe and efficient. Therefore, OCTA is committed to establishing and maintaining a work environment free from the influence of drug and alcohol.

The Orange County Transportation Authority certifies that it will strive to provide a drug-free workplace through the following steps:

1. Publishing a statement notifying employees that the unlawful manufacture, distribution, dispensing, possession, or use of a controlled substance is prohibited in OCTA's workplace and specifying the actions that will be taken against employees for violation of such prohibition.
2. Establishing an on-going drug-free awareness program to inform employees about:
   (a) The dangers of drug abuse in the workplace;
   (b) OCTA's policy of maintaining a drug-free workplace;
   (c) Potential dangers associated with the use of prescription (Rx) and over-the-counter (OTC) medications;
   (d) Any available drug counseling, rehabilitation, and employee assistance programs; and
   (e) The penalties that may be imposed upon employees for drug abuse violations occurring in the workplace.
3. Requiring that each employee, including those engaged in the performance of a grant or cooperative agreement, be given a copy of the statement required by paragraph one (1) above.
4. Notifying employees, in the statement required by paragraph one (1), that as a condition of employment under any grant or cooperative agreement the employees will:
   (a) Abide by the terms of the statement; and
   (b) Notify the employer in writing of his/her conviction for a violation of a criminal drug statute occurring in the workplace no later than five (5) calendar days after such conviction.

ATTACHMENT D

DRUG–FREE WORKPLACE ACT CERTIFICATION FOR A PUBLIC OR PRIVATE ENTITY

5. Notifying the Federal agency in writing within ten (10) calendar days after receiving notice from an employee under subparagraph four (4) (b) above or receiving actual notice of such conviction. Employers of convicted employees must provide notice, including position title, to every project officer or other designee on whose project activity the convicted employee was working, unless the Federal agency has designated a central point for the receipt of such notices. Notice shall include the identification number(s) of each affected grant or cooperative agreement.
6. Taking one of the following actions within thirty (30) calendar days of receiving notice under subparagraph four (4) (b) above, with respect to any employee who is so convicted:
   (a) Take appropriate personnel action against such an employee, up to and including employment termination, consistent with the requirements of the Rehabilitation Act of 1973, as amended; or
   (b) Require such employee to participate satisfactorily in drug abuse assistance or rehabilitation program approved for such purposes by a Federal, State or local health, law enforcement or other appropriate agency.
7. Making a good faith effort to continue to maintain a drug-free workplace through implementation of paragraphs one (1) through six (6) above.

OCTA's headquarters is located at the following address. Addresses of other OCTA workplace sites maintained by OCTA are either attached or available upon request.

Orange County Transportation Authority
550 South Main Street
PO BOX 14184
Orange, CA 92863-1584

Darrell Johnson
Chief Executive Officer
Orange County Transportation Authority

2-18-15
Date

ATTACHMENT E

DRUG AND ALCOHOL POLICY MANUAL TEST REASONS AND REQUIREMENTS TABLE

Test Reason	Drug Test Requirement	Alcohol Test Requirement
Bi-Annual Physical	OCTA	OCTA
Behavioral Contract	OCTA	OCTA
DMV Certification/Re-Certification	OCTA	OCTA
Fit for Duty	OCTA	OCTA
Follow-Up Test	DOT	DOT
Post Accident resulting in a fatality	DOT	DOT
Post Accident resulting in injury treatment away from scene	DOT	DOT
Post Accident resulting in any vehicle towed	DOT	DOT
Post Accident (none of the above or non-revenue service vehicle)	OCTA	OCTA
Pre-Employment/Post Offer (Safety-Sensitive)	DOT	OCTA
Probable Cause (Non-Safety Sensitive)	OCTA	OCTA
Random	DOT	DOT
Reasonable Suspicion (Safety-Sensitive)	DOT	DOT
Return to Duty	DOT	DOT
All of the above tests and reasons for testing are described in Section 5 of the Drug and Alcohol Policy Manual.		

DRUG AND ALCOHOL POLICY MANUAL

ATTACHMENTS—SECTION 9

ATTACHMENT F

CONTACT PERSONS

For more information or questions about the OCTA Drug and Alcohol Policy Manual or testing program, please contact a staff member in the Health, Safety, and Environmental Compliance Department at the telephone numbers listed below. Each of these Contact Persons are located at the OCTA Administrative Offices: 600 South Main Street; PO Box 14184; Orange, CA 92863-1584.

- Drug and Alcohol Program Manager/
  Designated Employer Representative (714) 560-5809

ATTACHMENT H

APPROVAL OF POLICY BY BOARD OF DIRECTORS

AFFILIATED AGENCIES

Orange County Transit District

Local Transportation Authority

Service Authority for Freeway Emergencies

Consolidated Transportation Service Agency

Congestion Management Agency

Service Authority for Abandoned Vehicles

APPROVAL OF POLICY BY BOARD OF DIRECTORS

MINUTE EXCERPT

The following is an excerpt from the Minutes of the Orange County Transportation Authority Board of Directors meeting held on **February 9, 2015.**

6. Drug and Alcohol Policy Manual

A motion was made by Director Murray, seconded by Director Spitzer, and declared passed by those present, to:

A. Approve the Orange County Transportation Authority's Drug and Alcohol Policy Manual.

B. Authorize the Chief Executive Officer to certify the Orange County Transportation Authority's Drug-Free Workplace Act Statement.

Director Nelson was not present to vote on this item.

The foregoing excerpt will be presented to the Board of Directors on February 23, 2015, as part of the completed minutes of the February 9, 2015, OCTA Board of Directors' meeting.

Laurena Weinert
Clerk of the Board

Dated: February 11, 2015

Orange County Transportation Authority
550 South Main Street / P.O. Box 14184 / Orange / California 92863-1584 / (714) 560-OCTA (6282)

ATTACHMENT C

2018 Revision

ATTACHMENT D

Performance Standards

OCTA may amend these Performance Standards. Any such amendments shall be provided to the Service Agent in writing.

Item	Task	Requirement	Penalty
1	Check-in employees and stamp arrival date/time on Authorization Forms	Within 05 minutes of employee arrival	Forfeit payment for each test not stamped per requirement.
2	Complete authorized tests and stamp departure date/time on Authorization Forms	Within 60 minutes of stamped arrival time	
3	Post test forms to the web-based application (Authorization, ATF, CCF)	Within 24 hours of departure time stamp	Forfeit payment for each test not posted per requirement.
4	Post drug test results and documents to the web-based application	As soon as available from lab/MRO but no later than 72 hours from the Date and Time of Collection shown on the CCF	
5	Notify OCTA via email of dilute negative results, cancelled tests, or other test result issues	As soon as available from lab/MRO but no later than 72 hours from the Date and Time of Collection shown on the CCF	Forfeit payment for each test not reported per requirement.
6	Notify OCTA verbally and by email of any BAT test result >0.00 and post result to the web-based application	Prior to releasing employee	

7	Notify OCTA verbally and by email of any positive drug test result and post result to the web-based application	Immediately upon knowledge, but no longer than 06 hours after MRO's stamped verification time	
8	Service Agent testing error that is uncorrectable and requires employee to return for retest	Not acceptable	Forfeit payment for uncorrectable test and for the retest
9	Respond to routine emails or other communications that do not indicate "URGENT" in the subject line or message.	Within 24 hours	Requires written explanation and corrective actions.
10	Respond to urgent emails or other communications that indicate "URGENT" in the subject line or message.	Within 03 hours	
11	Deliver monthly invoice and original testing documents to OCTA in a specified order	By day 15 of month	Required before payment
12	Minor ATF and CCF issues and errors correctable by form notations, as allowed by DOT/FTA regulations	Acceptable if found and corrected by Service Agent	Forfeit payment for each test not corrected by Service Agent
13	Loss of service availability (24/7/365) (Within reasonable control of Service Agent)	Not acceptable	$50.00 / hour of interrupted service
14	Provide AOC if required by FTA regulations	As required by FTA regulations	Forfeit payment for each test missing an AOC.
15	Violation of 49 CFR Part 655 or Part 40	Must not violate	Forfeit payment for each test in violation.

END OF PERFORMANCE STANDARDS

EXHIBIT B: COST AND PRICE FORMS

RFP 3-3068
EXHIBIT B

REQUEST FOR PROPOSALS (RFP) 3-3068

PRICE SUMMARY SHEET

Enter below the proposed price for the services described in the Scope of Work, Exhibit A. Prices shall include direct costs, indirect costs, tax, and profits. The Authority's intention is to award a time-and-expense price contract.

Initial Term: Effective Date – July 31, 2027

Description	*Year 1 Eff. Date – 7/31/25 Per Unit Cost*	*Year 2 8/1/25 – 7/31/26 Per Unit Cost*	*Year 3 8/1/26 – 7/31/27 Per Unit Cost*
DOT Physical Examination: pre-employment (including review of driver health history, blood pressure, urinalysis, vision, hearing whisper test and/or audiogram test, physical exam, and INCLUDING completion of Medical Examiner's Certificate MCSA-5876 and instructions)	$_____	$_____	$_____
DOT Physical Examination: DMV license renewal (including review of driver health history, blood pressure, urinalysis, vision, hearing whisper test and/or audiogram test, physical exam, and INCLUDING completion of Medical Examiner's Certificate MCSA-5876 and instructions)	$_____	$_____	$_____
Non-DOT Physical Examinations: pre-employment with current commercial drivers license (including review of driver health history, blood pressure, urinalysis, vision, hearing whisper test and/or audiogram test, physical exam, and EXCLUDES Medical Examiner's Certificate MCSA-5876)	$_____	$_____	$_____
Bloodborne Pathogens Hepatitis B Vaccinations	$_____	$_____	$_____
Post Vaccination Testing for Hepatitis B Antibodies (Titer)	$_____	$_____	$_____
Respiratory Protection Medical Evaluation / Certification	$_____	$_____	$_____
Pulmonary Function Test (PFT)	$_____	$_____	$_____
Respirator Fit Test	$_____	$_____	$_____

Full Range Audiogram	$_____	$_____	$_____
Glucoscan / Glucometer Finger Stick	$_____	$_____	$_____
DOT/Non-DOT Drug Screen (Urine)	$_____	$_____	$_____
DOT/Non-DOT Drug Screen (Oral Fluid)	$_____	$_____	$_____
DOT/Non-DOT Breath Alcohol Test	$_____	$_____	$_____

Option Term: August 1, 2027 – July 31, 2029

Description	***Year 4 8/1/27 - 7/31/28 Per Unit Cost***	***Year 5 8/1/28 – 7/31/29 Per Unit Cost***
DOT Physical Examination: pre-employment (including review of driver health history, blood pressure, urinalysis, vision, hearing whisper test and/or audiogram test, physical exam, and INCLUDING completion of Medical Examiner's Certificate MCSA-5876 and instructions)	$_____	$_____
DOT Physical Examination: DMV license renewal (including review of driver health history, blood pressure, urinalysis, vision, hearing whisper test and/or audiogram test, physical exam, and INCLUDING completion of Medical Examiner's Certificate MCSA-5876 and instructions)	$_____	$_____
Non-DOT Physical Examinations: pre-employment with current commercial drivers license (including review of driver health history, blood pressure, urinalysis, vision, hearing whisper test and/or audiogram test, physical exam, and EXCLUDES Medical Examiner's Certificate MCSA-5876)	$_____	$_____
Bloodborne Pathogens Hepatitis B Vaccinations	$_____	$_____
Post Vaccination Testing for Hepatitis B Antibodies (Titer)	$_____	$_____
Respiratory Protection Medical Evaluation / Certification	$_____	$_____
Pulmonary Function Test (PFT)	$_____	$_____

Respirator Fit Test	$_____	$_____
Full Range Audiogram	$_____	$_____
Glucoscan / Glucometer Finger Stick	$_____	$_____
DOT/Non-DOT Drug Screen (Urine)	$_____	$_____
DOT/Non-DOT Drug Screen (Oral Fluid)	$_____	$_____
DOT/Non-DOT Breath Alcohol Test	$_____	$_____

_____

1. I acknowledge receipt of RFP 3-3068 and Addenda No.(s) _____.

2. This offer shall remain firm for _____ days from the date of proposal.
(Minimum 120)

COMPANY NAME _____

ADDRESS _____

TELEPHONE _____

SIGNATURE OF PERSON
AUTHORIZED TO BIND OFFEROR _____

SIGNATURE'S NAME AND TITLE _____

DATE SIGNED _____

EXHIBIT C: PROPOSED AGREEMENT

PROPOSED AGREEMENT NO. C-3-3068

BETWEEN

ORANGE COUNTY TRANSPORTATION AUTHORITY

AND

_____

THIS AGREEMENT is effective this _____ day of _____, 2024 ("Effective Date"), by and between the Orange County Transportation Authority, 550 South Main Street, P.O. Box 14184, Orange, California 92863-1584, a public corporation of the State of California (hereinafter referred to as "AUTHORITY"), and , , , , (hereinafter referred to as "CLINIC").

WITNESSETH:

WHEREAS, AUTHORITY requires assistance from CLINIC to provide medical clinic services; and

WHEREAS, said work cannot be performed by the regular employees of AUTHORITY; and

WHEREAS, CLINIC has represented that it has the requisite personnel and experience, and is capable of performing such services; and

WHEREAS, CLINIC wishes to perform these services.

NOW, THEREFORE, it is mutually understood and agreed by AUTHORITY and CLINIC as follows:

ARTICLE 1. COMPLETE AGREEMENT

A. This Agreement, including all exhibits and documents incorporated herein and made applicable by reference, constitutes the complete and exclusive statement of the terms and conditions of this Agreement between AUTHORITY and CLINIC and it supersedes all prior representations, understandings and communications. The invalidity in whole or in part of any term or condition of this Agreement shall not affect the validity of other terms or conditions.

B. AUTHORITY's failure to insist in any one or more instances upon CLINIC's performance of any terms or conditions of this Agreement shall not be construed as a waiver or relinquishment of

AUTHORITY's right to such performance or to future performance of such terms or conditions and CLINIC's obligation in respect thereto shall continue in full force and effect. Changes to any portion of this Agreement shall not be binding upon AUTHORITY except when specifically confirmed in writing by an authorized representative of AUTHORITY by way of a written amendment to this Agreement and issued in accordance with the provisions of this Agreement.

ARTICLE 2. AUTHORITY DESIGNEE

The Chief Executive Officer of AUTHORITY, or designee, shall have the authority to act for and exercise any of the rights of AUTHORITY as set forth in this Agreement.

ARTICLE 3. SCOPE OF WORK

A. CLINIC shall perform the work necessary to complete in a manner satisfactory to AUTHORITY the services set forth in Exhibit A, entitled "Scope of Work," attached to and, by this reference, incorporated in and made a part of this Agreement. All services shall be provided at the times and places designated by AUTHORITY.

B. CLINIC shall provide the personnel listed below to perform the above-specified services, which persons are hereby designated as key personnel under this Agreement.

Names	Functions

C. No person named in paragraph B of this Article, or his/her successor approved by AUTHORITY, shall be removed or replaced by CLINIC, nor shall his/her agreed-upon function or level of commitment hereunder be changed, without the prior written consent of AUTHORITY. Should the services of any key person become no longer available to CLINIC, the resume and qualifications of the proposed replacement shall be submitted to AUTHORITY for approval as soon as possible, but in no event later than seven (7) calendar days prior to the departure of the incumbent key person, unless CLINIC is not provided with such notice by the departing employee. AUTHORITY shall respond to

CLINIC within seven (7) calendar days following receipt of these qualifications concerning acceptance of the candidate for replacement.

ARTICLE 4. TERM OF AGREEMENT

This Agreement shall commence upon execution by both parties, and shall continue in full force and effect through July 31, 2027 (Initial Term), unless earlier terminated or extended as provided in this Agreement.

A. AUTHORITY, at its sole discretion, may elect to extend the term of this Agreement for up to an additional twenty-four (24) months commencing August 1, 2027, and continuing through July 31, 2029 (Option Term), and thereupon require CLINIC to continue to provide services, and otherwise perform, in accordance with Exhibit A and at the amounts or rates set forth in Article 5, “Payment.”

B. AUTHORITY’s election to extend this Agreement beyond the Initial Term shall not diminish its right to terminate the Agreement for AUTHORITY’s convenience or CLINIC’s default as provided elsewhere in this Agreement. The “maximum term” of this Agreement shall be the period extending from commencement through July 31, 2029, which period encompasses the Initial Term and Option Term.

ARTICLE 5. PAYMENT

A. For CLINIC’s full and complete performance of its obligations under this Agreement and subject to the maximum cumulative payment obligation provisions set forth in Article 6, AUTHORITY shall pay CLINIC on a time-and-expense basis in accordance with the following provisions.

B. CLINIC shall invoice AUTHORITY on a monthly basis for payments corresponding to the work actually completed by CLINIC. COSULTANT shall not charge AUTHORITY for driving time. Work completed shall be documented in a monthly progress report prepared by CLINIC, which shall accompany each invoice submitted by CLINIC. AUTHORITY shall pay CLINIC at the hourly labor rates specified in Exhibit B, entitled "Price Summary Sheet," which is attached to and by this reference, incorporated in and made a part of this Agreement. These rates shall remain fixed for the term of this Agreement and are acknowledged to include CLINIC's overhead costs, general costs, administrative costs and profit. CLINIC shall also furnish such other information as may be requested by AUTHORITY

to substantiate the validity of an invoice. At its sole discretion, AUTHORITY may decline to make full payment until such time as CLINIC has documented to AUTHORITY's satisfaction that CLINIC has fully completed all work required. AUTHORITY's payment in full shall constitute AUTHORITY's final acceptance of CLINIC's work.

C. Invoices shall be submitted by CLINIC on a monthly basis and shall be submitted in duplicate to AUTHORITY's Accounts Payable office. CLINIC may also submit invoices electronically to AUTHORITY's Accounts Payable Department at vendorinvoices@octa.net. Each invoice shall be accompanied by the monthly progress report specified in paragraph B of this Article. AUTHORITY shall remit payment within thirty (30) calendar days of the receipt and approval of each invoice. Each invoice shall include the following information:

1. Agreement No. C-3-3068;

2. Specify the effort for which the payment is being requested;

3. The time period covered by the invoice;

4. Labor (staff name, hours charged, hourly billing rate, current charges, and cumulative charges) performed during the billing period;

5. Total monthly invoice (including project-to-date cumulative invoice amount);

6. Itemized expenses including support documentation incurred during the billing period;

7. Monthly Progress Report;

8. Certification signed by the CLINIC or his/her designated alternate that a) The invoice is a true, complete and correct statement of reimbursable costs and progress; b) The backup information included with the invoice is true, complete and correct in all material respects; c) All payments due and owing to subcontractors and suppliers have been made; d) Timely payments will be made to subcontractors and suppliers from the proceeds of the payments covered by the certification and; e) The invoice does not include any amount which CLINIC intends to withhold or retain from a subcontractor or supplier unless so identified on the invoice.

9. Any other information as agreed or requested by AUTHORITY to substantiate the validity of an invoice.

ARTICLE 6. MAXIMUM OBLIGATION

Notwithstanding any provisions of this Agreement to the contrary, AUTHORITY and CLINIC mutually agree that AUTHORITY's maximum cumulative payment obligation (including obligation for CLINIC's profit) shall be _____ Dollars ($ _____.00) which shall include all amounts payable to CLINIC for its subcontracts, leases, materials and costs arising from, or due to termination of, this Agreement.

ARTICLE 7. NOTICES

All notices hereunder and communications regarding the interpretation of the terms of this Agreement, or changes thereto, shall be effected by delivery of said notices in person or by depositing said notices in the U.S. mail, registered or certified mail, returned receipt requested, postage prepaid and addressed as follows:

To CLINIC:	To AUTHORITY:
	Orange County Transportation Authority
	550 South Main Street
	P.O. Box 14184
,	Orange, CA 92863-1584
ATTENTION:	ATTENTION: Jackie Le
Title:	Title: Senior Contract Administrator
Phone:	Phone: (714) 560-5486
Email:	Email: jle@octa.net

ARTICLE 8. INDEPENDENT CONTRACTOR

A. CLINIC's relationship to AUTHORITY in the performance of this Agreement is that of an independent contractor. CLINIC's personnel performing services under this Agreement shall at all times be under CLINIC's exclusive direction and control and shall be employees of CLINIC and not employees

of AUTHORITY. CLINIC shall pay all wages, salaries and other amounts due its employees in connection with this Agreement and shall be responsible for all reports and obligations respecting them, such as social security, income tax withholding, unemployment compensation, workers' compensation and similar matters.

B. Should CLINIC's personnel or a state or federal agency allege claims against AUTHORITY involving the status of AUTHORITY as employer, joint or otherwise, of said personnel, or allegations involving any other independent contractor misclassification issues, CLINIC shall defend and indemnify AUTHORITY in relation to any allegations made.

ARTICLE 9. INSURANCE

A. CLINIC shall procure and maintain insurance coverage in full force and effect during the entire term of the Agreement. Coverage shall be full coverage and not subject to self-insurance provisions. CLINIC shall provide the following insurance coverage:

1. Commercial General Liability, to include Products/Completed Operations, Independent Contractors', Contractual Liability, and Personal Injury Liability, and Property Damage with a minimum limit of $1,000,000 per occurrence, $2,000,000 general aggregate and $2,000,000 Products/Completed Operations aggregate;

2. Automobile Liability Insurance to include owned, hired and non-owned autos with a combined single limit of $1,000,000 for each accident;

3. Workers' Compensation with limits as required by the State of California including a Waiver of Subrogation in favor of AUTHORITY, its officers, directors and employees; and

4. Employers' Liability with minimum limits of $1,000,000 per accident, $1,000,000 policy limit-disease, and $1,000,000 policy limit employee-disease.

5. Professional Liability with minimum limits of $1,000,000.

B. Proof of such coverage, in the form of a certificate of insurance and an insurance policy blanket additional insured endorsement, designating AUTHORITY, its officers, directors and employees as additional insureds on general liability and automobile liability, as required by Agreement. Proof of

insurance coverage must be received by AUTHORITY within ten (10) calendar days from the effective date of the Agreement and prior to commencement of any work. Such insurance shall be primary and non-contributive to any insurance or self-insurance maintained by AUTHORITY. Furthermore, AUTHORITY reserves the right to request certified copies or review all related insurance policies, in response to a related loss.

C. CLINIC shall include on the face of the certificate of insurance the Agreement No. C-3-3068 and, the Senior Contract Administrator's Name, Jackie Le.

D. CLINIC shall also include in each subcontract, the stipulation that subcontractors shall maintain insurance coverage in the amounts required of CLINIC as provided in the Agreement. Subcontractors will be required to include AUTHORITY as additional insureds on the Commercial General Liability, and Auto Liability insurance policies.

E. Insurer must provide AUTHORITY with at least thirty (30) days' prior notice of cancellation or material modification of coverage, and ten (10) days' prior notice for non-payment of premium.

ARTICLE 10. ORDER OF PRECEDENCE

Conflicting provisions hereof, if any, shall prevail in the following descending order of precedence: (1) the provisions of this Agreement, including all exhibits; (2) the provisions of RFP 3-3068; (3) CLINIC's proposal dated _____; (4) all other documents, if any, cited herein or incorporated by reference.

ARTICLE 11. CHANGES

By written notice or order, AUTHORITY may, from time to time, order work suspension and/or make changes in the general scope of this Agreement, including, but not limited to, the services furnished to AUTHORITY by CLINIC as described in the Scope of Work. If any such work suspension or change causes an increase or decrease in the price of this Agreement, or in the time required for its performance, CLINIC shall promptly notify AUTHORITY thereof and assert its claim for adjustment within ten (10) calendar days after the change or work suspension is ordered, and an equitable adjustment shall be negotiated. However, nothing in this clause shall excuse CLINIC from proceeding immediately with the

Agreement as changed.

ARTICLE 12. DISPUTES

A. Except as otherwise provided in this Agreement, when a dispute arises between CLINIC and AUTHORITY, the project managers shall meet to resolve the issue. If project managers do not reach a resolution, the dispute will be decided by AUTHORITY's Director of Contracts Administration and Materials Management (CAMM), who shall reduce the decision to writing and mail or otherwise furnish a copy thereof to CLINIC. The decision of the Director, CAMM, shall be the final and conclusive administrative decision.

B. Pending final decision of a dispute hereunder, CLINIC shall proceed diligently with the performance of this Agreement and in accordance with the decision of AUTHORITY's Director, CAMM. Nothing in this Agreement, however, shall be construed as making final the decision of any AUTHORITY official or representative on a question of law, which questions shall be settled in accordance with the laws of the State of California.

ARTICLE 13. TERMINATION

A. AUTHORITY may terminate this Agreement for its convenience at any time, in whole or part, by giving CLINIC written notice thereof. Upon said notice, AUTHORITY shall pay CLINIC its allowable costs incurred to date of termination and those allowable costs determined by AUTHORITY to be reasonably necessary to effect such termination. Thereafter, CLINIC shall have no further claims against AUTHORITY under this Agreement.

B. In the event either Party defaults in the performance of any of their obligations under this Agreement or breaches any of the provisions of this Agreement, the non-defaulting Party shall have the option to terminate this Agreement upon thirty (30) days' prior written notice to the other Party. Upon receipt of such notice, CLINIC shall immediately cease work, unless the notice from AUTHORITY provides otherwise. Upon receipt of the notice from AUTHORITY, CLINIC shall submit an invoice for work and/or services performed prior to the date of termination. AUTHORITY shall pay CLINIC for work and/or services satisfactorily provided to the date of termination in compliance with this

Agreement. Thereafter, CLINIC shall have no further claims against AUTHORITY under this Agreement. AUTHORITY shall not be liable for any claim of lost profits or damages for such termination.

ARTICLE 14. INDEMNIFICATION

CLINIC shall indemnify, defend and hold harmless AUTHORITY, its officers, directors, employees and agents (indemnities) from and against any and all claims (including attorneys' fees and reasonable expenses for litigation or settlement) for any loss or damages, bodily injuries, including death, damage to or loss of use of property caused by the negligent acts, omissions or willful misconduct by CLINIC, its officers, directors, employees, agents, subcontractors or suppliers in connection with or arising out of the performance of this Agreement.

ARTICLE 15. ASSIGNMENTS AND SUBCONTRACTS

A. Neither this Agreement nor any interest herein nor claim hereunder may be assigned by CLINIC either voluntarily or by operation of law, nor may all or any part of this Agreement be subcontracted by CLINIC, without the prior written consent of AUTHORITY. Consent by AUTHORITY shall not be deemed to relieve CLINIC of its obligations to comply fully with all terms and conditions of this Agreement.

B. AUTHORITY hereby consents to CLINIC subcontracting portions of the Scope of Work to the parties identified below for the functions described in CLINIC's proposal. CLINIC shall include in the subcontract agreement the stipulation that CLINIC, not AUTHORITY, is solely responsible for payment to the subcontractor for the amounts owing and that the subcontractor shall have no claim, and shall take no action, against AUTHORITY, its officers, directors, employees or sureties for nonpayment by CLINIC.

Subcontractor Name/Addresses	**Subcontractor Functions**

ARTICLE 16. AUDIT AND INSPECTION OF RECORDS

CLINIC shall provide AUTHORITY, or other agents of AUTHORITY, such access to CLINIC's

accounting books, records, payroll documents and facilities, as AUTHORITY deems necessary. CLINIC shall maintain such books, records, data and documents in accordance with generally accepted accounting principles and shall clearly identify and make such items readily accessible to such parties during CLINIC's performance hereunder and for a period of four (4) years from the date of final payment by AUTHORITY. AUTHORITY's right to audit books and records directly related to this Agreement shall also extend to all first-tier subcontractors identified in Article 15 of this Agreement. CLINIC shall permit any of the foregoing parties to reproduce documents by any means whatsoever or to copy excerpts and transcriptions as reasonably necessary.

ARTICLE 17. CONFLICT OF INTEREST

A. CLINIC agrees to avoid organizational conflicts of interest. An organizational conflict of interest means that due to other activities, relationships or contracts, the CLINIC is unable, or potentially unable to render impartial assistance or advice to AUTHORITY; CLINIC's objectivity in performing the work identified in the Scope of Work is or might be otherwise impaired; or CLINIC has an unfair competitive advantage. CLINIC is obligated to fully disclose to AUTHORITY in writing Conflict of Interest issues as soon as they are known to CLINIC. All disclosures must be submitted in writing to AUTHORITY pursuant to the Notice provision herein. This disclosure requirement is for the entire term of this Agreement.

B. If AUTHORITY determines that CLINIC, its employees, or subcontractors are subject to disclosure requirements under the Political Reform Act (Government Code section 81000 et seq.), CLINIC and its required employees and subcontractors shall complete and file Statements of Economic Interest (Form 700) with AUTHORITY's Clerk of the Board disclosing all required financial interests.

ARTICLE 18. CODE OF CONDUCT

CLINIC agrees to comply with AUTHORITY's Code of Conduct as it relates to Third-Party contracts which is hereby referenced and by this reference is incorporated herein. CLINIC agrees to include these requirements in all of its subcontracts.

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ARTICLE 19. PROHIBITION ON PROVIDING ADVOCACY SERVICES

CLINIC and all subcontractors performing work under this Agreement, shall be prohibited from concurrently representing or lobbying for any other party competing for a contract with AUTHORITY, either as a prime CLINIC or subcontractor. Failure to refrain from such representation may result in termination of this Agreement.

ARTICLE 20. FEDERAL, STATE AND LOCAL LAWS

CLINIC warrants that in the performance of this Agreement, it shall comply with all applicable federal, state and local laws, statutes and ordinances and all lawful orders, rules and regulations promulgated thereunder.

ARTICLE 21. EQUAL EMPLOYMENT OPPORTUNITY

In connection with its performance under this Agreement, CLINIC shall not discriminate against any employee or applicant for employment because of race, religion, color, sex, age or national origin. CLINIC shall take affirmative action to ensure that applicants are employed, and that employees are treated during their employment, without regard to their race, religion, color, sex, age or national origin. Such actions shall include, but not be limited to, the following: employment, upgrading, demotion or transfer; recruitment or recruitment advertising; layoff or termination; rates of pay or other forms of compensation; and selection for training, including apprenticeship.

ARTICLE 22. PROHIBITED INTERESTS

CLINIC covenants that, for the term of this Agreement, no director, member, officer or employee of AUTHORITY during his/her tenure in office or for one (1) year thereafter shall have any interest, direct or indirect, in this Agreement or the proceeds thereof.

ARTICLE 23. OWNERSHIP OF REPORTS AND DOCUMENTS

A. The originals of all letters, documents, reports and other products and data produced under this Agreement shall be delivered to, and become the property of AUTHORITY. Copies may be made for CLINIC's records but shall not be furnished to others without written authorization from AUTHORITY. Such deliverables shall be deemed works made for hire and all rights in copyright therein shall be retained

by AUTHORITY.

B. All ideas, memoranda, specifications, plans, manufacturing, procedures, drawings, descriptions, and all other written information submitted to CLINIC in connection with the performance of this Agreement shall not, without prior written approval of AUTHORITY, be used for any purposes other than the performance under this Agreement, nor be disclosed to an entity not connected with the performance of the project. CLINIC shall comply with AUTHORITY's policies regarding such material. Nothing furnished to CLINIC, which is otherwise known to CLINIC or is or becomes generally known to the related industry shall be deemed confidential. CLINIC shall not use AUTHORITY's name, photographs of the project, or any other publicity pertaining to the project in any professional publication, magazine, trade paper, newspaper, seminar or other medium without the express written consent of AUTHORITY.

C. No copies, sketches, computer graphics or graphs, including graphic artwork, are to be released by CLINIC to any other person or agency except after prior written approval by AUTHORITY, except as necessary for the performance of services under this Agreement. All press releases, including graphic display information to be published in newspapers, magazines, etc., are to be handled only by AUTHORITY unless otherwise agreed to by CLINIC and AUTHORITY.

ARTICLE 24. PATENT AND COPYRIGHT INFRINGEMENT

A. In lieu of any other warranty by AUTHORITY or CLINIC against patent or copyright infringement, statutory or otherwise, it is agreed that CLINIC shall defend at its expense any claim or suit against AUTHORITY on account of any allegation that any item furnished under this Agreement or the normal use or sale thereof arising out of the performance of this Agreement, infringes upon any presently existing U.S. letters patent or copyright and CLINIC shall pay all costs and damages finally awarded in any such suit or claim, provided that CLINIC is promptly notified in writing of the suit or claim and given authority, information and assistance at CLINIC's expense for the defense of same. However, CLINIC will not indemnify AUTHORITY if the suit or claim results from: (1) AUTHORITY's alteration of a deliverable, such that said deliverable in its altered form infringes upon any presently existing U.S. letters

patent or copyright; or (2) the use of a deliverable in combination with other material not provided by CLINIC when such use in combination infringes upon an existing U.S. letters patent or copyright.

B. CLINIC shall have sole control of the defense of any such claim or suit and all negotiations for settlement thereof. CLINIC shall not be obligated to indemnify AUTHORITY under any settlement made without CLINIC's consent or in the event AUTHORITY fails to cooperate fully in the defense of any suit or claim, provided, however, that said defense shall be at CLINIC's expense. If the use or sale of said item is enjoined as a result of such suit or claim, CLINIC, at no expense to AUTHORITY, shall obtain for AUTHORITY the right to use and sell said item, or shall substitute an equivalent item acceptable to AUTHORITY and extend this patent and copyright indemnity thereto.

ARTICLE 25. FINISHED AND PRELIMINARY DATA

A. All of CLINIC's finished technical data, including but not limited to illustrations, photographs, tapes, software, software design documents, including without limitation source code, binary code, all media, technical documentation and user documentation, photoprints and other graphic information required to be furnished under this Agreement, shall be AUTHORITY's property upon payment and shall be furnished with unlimited rights and, as such, shall be free from proprietary restriction except as elsewhere authorized in this Agreement. CLINIC further agrees that it shall have no interest or claim to such finished, AUTHORITY-owned, technical data; furthermore, said data is subject to the provisions of the Freedom of Information Act, 5 USC 552.

B. It is expressly understood that any title to preliminary technical data is not passed to AUTHORITY but is retained by CLINIC. Preliminary data includes roughs, visualizations, software design documents, layouts and comprehensives prepared by CLINIC solely for the purpose of demonstrating an idea or message for AUTHORITY's acceptance before approval is given for preparation of finished artwork. Preliminary data title and right thereto shall be made available to AUTHORITY if CLINIC causes AUTHORITY to exercise Article 13, and a price shall be negotiated for all preliminary data.

ARTICLE 26. HEALTH AND SAFETY REQUIREMENT

CLINIC shall comply with all the requirements set forth in Exhibit _, Level 2 Safety Specifications.

ARTICLE 27. LIMITATION ON GOVERNMENTAL DECISIONS

CLINIC shall not make, participate in making, or use its position to influence any governmental decisions as defined by the Political Reform Act, Government Code section 8100 et seq., and the implementing regulations in Title 2 of the California Code of Regulations section 18110 et seq. CLINIC's personnel performing services under this Agreement shall not authorize or direct any actions, votes, appoint any person, obligate, or commit AUTHORITY to any course of action or enter into any contractual agreement on behalf of AUTHORITY. In addition, CLINIC's personnel shall not provide information, an opinion, or a recommendation for the purpose of affecting a decision without significant intervening substantive review by AUTHORITY personnel, counsel, and management.

ARTICLE 28. FORCE MAJEURE

Either party shall be excused from performing its obligations under this Agreement during the time and to the extent that it is prevented from performing by an unforeseeable cause beyond its control, including but not limited to: any incidence of fire, flood; acts of God; commandeering of material, products, plants or facilities by the federal, state or local government; national fuel shortage; or a material act or omission by the other party; when satisfactory evidence of such cause is presented to the other party, and provided further that such nonperformance is unforeseeable, beyond the control and is not due to the fault or negligence of the party not performing.

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IN WITNESS WHEREOF, the parties hereto have caused this Agreement No. C-3-3068 to be executed as of the date of the last signature below.

CLINIC

By: _____

ORANGE COUNTY TRANSPORTATION AUTHORITY

By: _____
Darrell E. Johnson
Chief Executive Officer

APPROVED AS TO FORM:

By: _____
James M. Donich
General Counsel

APPROVED AS TO FORM:

By: _____
Maggie McJilton
Executive Director, People and Community Engagement

EXHIBIT D: STATUS OF PAST AND PRESENT FORM

STATUS OF PAST AND PRESENT CONTRACTS FORM

On the form provided below, Offeror/Bidder shall list the status of past and present contracts where the firm has either provided services as a prime vendor or a subcontractor during the past five (5) years in which the contract has been the subject of or may be involved in litigation with the contracting authority. This includes, but is not limited to, claims, settlement agreements, arbitrations, administrative proceedings, and investigations arising out of the contract.

A separate form must be completed for each contract. Offeror/Bidder shall provide an accurate contact name and telephone number for each contract and indicate the term of the contract and the original contract value. Offeror/Bidder shall also provide a brief summary and the current status of the litigation, claims, settlement agreements, arbitrations, administrative proceedings, or investigations. If the contract was terminated, list the reason for termination.

Offeror/Bidder shall have an ongoing obligation to update the Authority with any changes to the identified contracts and any new litigation, claims, settlement agreements, arbitrations, administrative proceedings, or investigations that arise subsequent to the submission of the bid. Each form must be signed by an officer of the Offeror/Bidder confirming that the information provided is true and accurate.

Project city/agency/other:
Contact Name: **Phone:**
Project Award Date: **Original Contract Value:**
Term of Contract:
(1) Litigation, claims, settlements, arbitrations, or investigations associated with contract:
(2) Summary and Status of contract:
(3) Summary and Status of action identified in (1):
(4) Reason for termination, if applicable:

By signing this Form entitled “Status of Past and Present Contracts,” I am affirming that all of the information provided is true and accurate.

Name	Signature
Title	Date

Revised. 03/16/2018

EXHIBIT E: CAMPAIGN CONTRIBUTION DISCLOSURE FORM

CAMPAIGN CONTRIBUTION DISCLOSURE FORM

Information Sheet

ORANGE COUNTY TRANSPORTATION AUTHORITY

The attached Campaign Contribution Disclosure Form must be completed by applicants for, or persons who are the subject of, any proceeding involving a license, permit, or other entitlement for use pending before the Board of Directors of the OCTA or any of its affiliated agencies. (Please see next page for definitions of these terms.)

IMPORTANT NOTICE

Basic Provisions of Government Code Section 84308

A. If you are an applicant for, or the subject of, any proceeding involving a license, permit, or other entitlement for use, you are prohibited from making a campaign contribution of more than $250 to any board member or his or her alternate. This prohibition begins on the date your application is filed or the proceeding is otherwise initiated, and the prohibition ends three months after a final decision is rendered by the Board of Directors. In addition, no board member or alternate may solicit or accept a campaign contribution of more than $250 from you during this period.

B. These prohibitions also apply to your agents, and, if you are a closely held corporation, to your majority shareholder as well. These prohibitions also apply to your subcontractor(s), joint venturer(s), and partner(s) in this proceeding. Also included are parent companies and subsidiary companies directed and controlled by you, and political action committees directed and controlled by you.

C. You must file the attached disclosure form and disclose whether you or your agent(s) have in the aggregate contributed more than $250 to any board member or his or her alternate during the 12-month period preceding the filing of the application or the initiation of the proceeding.

D. If you or your agent have in the aggregate contributed more than $250 to any individual board member or his/or her alternate during the 12 months preceding the decision on the application or proceeding, that board member or alternate must disqualify himself or herself from the decision. However, disqualification is not required if the board member or alternate returns the campaign contribution within 30 days from the time the director knows, or should have known, about both the contribution and the fact that you are a party in the proceeding. The Campaign Contribution Disclosure Form should be completed and filed with your proposal, or with the first written document you file or submit after the proceeding commences.

1. A proceeding involving "a license, permit, or other entitlement for use" includes all business, professional, trade and land use licenses and permits, and all other entitlements for use, including all entitlements for land use, all contracts (other than competitively bid, labor or personal employment contracts), and all franchises.

2. Your "agent" is someone who represents you in connection with a proceeding involving a license, permit or other entitlement for use. If an individual acting as an agent is also acting in his or her capacity as an employee or member of a law, architectural, engineering, consulting firm, or similar business entity, both the business entity and the individual are “agents.”

3. To determine whether a campaign contribution of more than $250 has been made by you, campaign contributions made by you within the preceding 12 months must be aggregated with those made by your agent within the preceding 12 months or the period of the agency, whichever is shorter. Contributions made by your majority shareholder (if a closely held corporation), your subcontractor(s), your joint venturer(s), and your partner(s) in this proceeding must also be included as part of the aggregation. Campaign contributions made to different directors or their alternates are not aggregated.

4. A list of the members and alternates of the Board of Directors is attached.

This notice summarizes the major requirements of Government Code Section 84308 of the Political Reform Act and California Code of Regulations, Title 2 Sections 18438-18438.8.

ORANGE COUNTY TRANSPORTATION AUTHORITY
CAMPAIGN CONTRIBUTION DISCLOSURE FORM

RFP Number: _____ RFP Title: _____

Was a campaign contribution made to any OCTA Board Member within the preceding 12 months, regardless of dollar amount of the contribution by either the proposing firm, proposed subconsultants and/or agent/lobbyist? Yes ____ No_____

If no, please sign and date below.

If yes, please provide the following information:

Prime Contractor Firm Name: _____

Contributor or Contributor Firm's Name: _____

Contributor or Contributor Firm's Address: _____

_____

Is Contributor:

- The Prime Contractor Yes___ No ___
- Subconsultant Yes___ No ___
- Agent/Lobbyist hired by Prime to represent the Prime in this RFP Yes___ No ___

Note: Under the State of California Government Code section 84308 and California Code of Regulations, Title 2, Section 18438, campaign contributions made by the Prime Contractor and the Prime Contractor's agent/lobbyist who is representing the Prime Contractor in this RFP must be aggregated together to determine the total campaign contribution made by the Prime Contractor.

_____

Identify the Board Member(s) to whom you, your subconsultants, and/or agent/lobbyist made campaign contributions, the name of the contributor, the dates of contribution(s) in the preceding 12 months and dollar amount of the contribution. Each date must include the exact month, day, and year of the contribution.

Name of Board Member: _____

Name of Contributor: _____

Date(s) of Contribution(s): _____

Amount(s): _____

Name of Board Member: _____

Name of Contributor: _____

Date(s) of Contribution(s): _____

Amount(s): _____

Date: _____ _____
Signature of Contributor

_____ _____
Print Firm Name Print Name of Contributor

ORANGE COUNTY TRANSPORTATION AUTHORITY
AND AFFILIATED AGENCIES

Board of Directors

Tam Nguyen, Chairman

Doug Chaffee, Vice Chairman

Ashleigh Aiken, Director

Valerie Amezcua, Director

Andrew Do, Director

Jon Dumitru, Director

Jamey Federico, Director

Katrina Foley, Director

Patrick Harper, Director

Michael Hennessey, Director

Fred Jung, Director

Farrah Khan, Director

Stephanie Klopfenstein, Director

Vicente Sarmiento, Director

John Stephens, Director

Donald Wagner, Director

EXHIBIT F: SAFETY SPECIFICATIONS

LEVEL 2 STANDARD HEALTH, SAFETY AND ENVIRONMENTAL SPECIFICATIONS

PART I – GENERAL

1.1 GENERAL HEALTH, SAFETY & ENVIRONMENTAL REQUIREMENTS

A. The Contractor, its subcontractors, suppliers, and employees have the obligation to comply with all Authority health, safety and environmental compliance department (HSEC), requirements of this safety specification, project site requirements, and bus yard safety rules as well as all federal, state, and local regulations pertaining to scope of work or agreements with the Authority. Additionally, manufacturer requirements are considered incorporated by reference as applicable to this scope of work.

B. Observance of repeated unsafe acts or conditions, serious violation of safety standards, non-conformance of Authority health, safety and environmental compliance department (HSEC) requirements, or disregard for the intent of these safety specifications to protect people and property, by Contractor or its subcontractors may be reason for termination of scope or agreements with the Authority, at the sole discretion of the Authority.

C. INJURY AND ILLNESS PREVENTION PROGRAM

The Contractor shall comply with CCR Title 8, Section with California Code of Regulations (CCR) Title 8, Section 3203. The intent and elements of the IIPP shall be implemented and enforced by the Contractor and its sub-tier contractors, suppliers, and vendors. The program shall be provided to the Authority's Project Manager, upon request, within 72 hours.

D. SUBSTANCE ABUSE PREVENTION PROGRAM

Contractor shall comply with the Policy or Program of the Company's Substance Abuse Prevention Policy that complies with the most recent Drug Free Workplace Act. The program shall be provided to the Authority's Project Manager, upon request, within 72 hours.

E. HAZARD COMMUNICATION PROGRAM

1. Contractor shall comply with CCR Title 8, Section 5194 Hazard Communication Standard. Prior to use on Authority property and/or project work areas Contractor shall provide the Authority Project Manager copies of SDS for all applicable products used, if any. The program shall be provided to the Authority's Project Manager, upon request, within 72 hours.

2. All chemicals including paint, solvents, detergents and similar substances shall comply with South Coast Air Quality Management District (SCAQMD) rules 103, 1113, and 1171.

F. STORM WATER POLLUTION PREVENTION PLAN

1. The Contractor shall protect property and water resources from fuels and similar products throughout the duration of the contract. Contractor shall comply with Storm Water Pollution Prevention Plan (SWPPP) requirements. The program or plan if required by scope shall be provided to the Authority's Project Manager, upon request, within 72 hours.

G. DESIGNATED HEALTH, SAFETY, ENVIRONMENTAL (HSE) REPRESENTATIVE

1. Upon contract award, the contractor within 10 business days shall designate a health and safety representative and provide a resume and qualifications to the Authority project manager, upon request, within 72 hours.

2. This person shall be a Competent or Qualified Individual as defined by the Occupational, Safety, and Health Administration (OSHA), familiar with applicable CCR Title 8 Standards, and has the authority to affect changes in work procedures that may have associated cost, schedule and budget impacts.

3. The Contractor's HSE Representative is subject to acceptance by the Authority Project Manager, and the HSEC Department. All contact information of the HSE Representative (name, phone, and fax and pager/cell phone number) shall be provided to the Authority Project Manager, upon request, within 72 hours.

4. The Contractor's HSE Representative shall hold a current certification from the Board of Certified Safety Professionals (BCSP) and have five years of demonstrated construction/scope experience enforcing HSE compliance on construction, industrial or similar project scopes. The designated HSE Representative shall participate in any required HSE related submittals. The Authority reserves the right to allow for an exception and to modify these minimum qualification requirements for unforeseen circumstances, at the sole discretion of the Authority Project Manager and HSEC Department Manager.

5. Competent Individual means an individual who is capable of identifying existing and predictable hazards in the surroundings or working conditions which are unsanitary, hazardous, or dangerous to employees and/or property, and who has authorization to take prompt corrective measures to eliminate them.

6. Qualified Individual means an individual who by possession of a recognized degree, certificate, certification or professional standing, or who by extensive knowledge, training, and experience, has successfully demonstrated his/her ability to solve or resolve problems relating to the subject matter, the work, or the Project.

H. SCOPE PLANNING

Prior to any scope work activity or task, the Contractor shall evaluate the hazards of the scope of work and the work environment to ensure proper control measures are identified for employee public and property protection measures to prevent incidents. This evaluation shall be implemented by developing a written site specific Job Hazard Analysis (JHA) or similar tool designed for planning the work to prevent incidents. The plan shall be provided to the Authority's Project Manager, upon request, within 72 hours.

I. ORIENTATION

1. The Contractor shall conduct and document a project site safety orientation for all Contractor personnel, subcontractors, suppliers, vendors, and new employees assigned to the project prior to performing any work on Authority projects. The safety orientation at a minimum shall include, as applicable, Personal Protection Equipment (PPE) requirements, eye protection, ANSI class 2 or 3 reflective vests, designated smoking, eating, and parking areas, traffic speed limit and routing, cell phone policy, and barricade requirements. When required by scope, additional orientation shall include fall protection, energy isolation/lock-out/tag-out (LOTO), confined space, hot work permit, security requirements, and similar project safety requirements.

2. Copies of orientation documents shall be provided to the Authority Project Manager within 72 hours upon request.

J. TRAFFIC & PARKING

The Contractor shall ensure that all Contractor vehicles, including those of their subcontractors, suppliers, vendors and employees are parked in designated parking areas, personal vehicles shall be parked in the employee parking lot, work vehicles required in the maintenance area of a bus base shall be identified by company name and/or logo, covered by the company insurance, and comply with traffic routes, and posted traffic signs in areas other than the employee parking lots. Vehicles without appropriate company name and logo are considered personal vehicles and not allowed in the maintenance area of the bus base.

K. GENERAL PROVISIONS

1. The Contractor shall provide all necessary tools, equipment, and related safety protective devices to execute the scope of work in compliance with Authority's HSEC requirements, CCR Title 8 Standards, and recognized safe work practices.

2. The Contractor shall immediately notify the Authority's Project Manager whenever local, state or federal regulatory agency personnel are identified as being onsite.

3. The Authority HSEC requirements, and references contained within this scope of work shall not be considered all-inclusive as to the hazards that might be encountered. Safe work practices shall be pre-planned and performed, and safe conditions shall be maintained during the course of this work scope.

4. The Contractor shall specifically acknowledge that it has primary responsibility to prevent and correct all health, safety and environmental hazards for which it and its employees, or its subcontractors (and their employees) are responsible. The Contractor shall further acknowledge their expertise in recognition and prevention of hazards in the operations for which they are responsible, that the Authority may not have such expertise, and is relying upon the Contractor for such expertise. The Authority retains the right to notify the Contractor of potential hazards and request the Contractor to evaluate and, as necessary, to eliminate those hazards.

5. The Contractor shall instruct all its employees, and all associated sub-contractors under contract with the Contractor who work on Authority property in the recognition, identification, and avoidance of unsafe acts and/or conditions applicable to its work.

6. California Code of Regulations (CCR) Title 8 Standards are minimum requirements, and each Contractor is encouraged to exceed minimum requirements. When the Contractor safety requirements exceed statutory standards, the more stringent requirements shall be achieved for the safeguard of the public and workers.

1.2 ENVIROMENTAL REQUIREMENTS

A. The Contractor shall comply with Federal, State, county, municipal, and other local laws and regulations pertaining to the environment, including noise, aesthetics, air quality, water quality, contaminated soils, hazardous waste, storm water, and resources of archaeological significance. Expense of compliance with these laws and regulations is considered included in the agreement. Contractor shall provide water used for dust control, or for pre-wetting areas to be paved, as required; no payment will be made by OCTA for this water.

B. The Contractor shall prevent pollution of storm drains, rivers, streams, irrigation ditches, and reservoirs with sediment or other harmful materials. Fuels, oils, bitumen, calcium chloride, cement, or other contaminants that would contribute to water pollution shall not be dumped into or placed where they will leach into storm drains, rivers, streams, irrigation ditches, or reservoirs. If operating equipment in streambeds or in and around open waters, protect the quality of ground water, wetlands, and surface waters.

C. The Contractor shall protect adjacent properties and water resources from erosion and sediment damage throughout the duration of the contract. Contractor shall comply with applicable NPDES permits and Storm Water Pollution Prevention Plan (SWPPP) requirements.

D. Contractor shall comply with all applicable EPA, Cal EPA, Cal Recycle, DTSC, SCAQMD, local, state, county and city standards, rules and regulations for hazardous and special waste handling, recycling and/ disposal. At a minimum, Contractor shall ensure compliance where applicable with SCAQMD Rule 1166, CCR Title 8, Section 5192, 29 CFR Subpart 1910.120, 49 CFR Part 172, Subpart H, 40 CFR Subpart 265.16 and CCR Title 22 Section 6625.16. Contractor shall provide OCTA a schedule of all hazardous waste and special or industrial waste disposal dates in advance of transport date. Only authorized OCTA personnel shall sign manifests for OCTA generated wastes. Contractor shall ensure that only current registered transporters are used for disposal of hazardous waste and industrial wastes. The Contractor shall obtain approval from OCTA for the disposal site locations in advance of scheduled transport date.

1.3 INCIDENT NOTIFICATION AND INVESTIGATION

A. The Authority shall be promptly notified of any of the following types of incidents including but not limited to:

1. Damage incidents of property (incidents involving third party, contractor or Authority property damage);

2. Reportable and/or Recordable injuries (as defined by the U. S. Occupational Safety and Health Administration), a minor injury, and near miss incidents;

3. Incidents impacting the environment, i.e. spills or releases on Authority property.

B. Notifications shall be made to Authority representatives, employees and/or agents. This includes incidents occurring to contractors, vendors, visitors, or members of the public that arise from the performance of Authority contract work. An immediate verbal notice followed by a written incident investigation report shall be submitted to Authority's Project Manager within 24 hours of the incident.

C. A final written incident investigative report shall be submitted within seven (7) calendar days and include the following information. The Current Status of anyone injured, photos of the incident area, detailed description of what happened, Investigative photos of the existing conditions and area around the injury/incident scene, the contributing factors that lead to the incident occurrence, a copy of the company policy or procedure associated with the incident and evaluation of effectiveness, copy of task planning documentation, copy of the Physician's first report of injury, copy of Cal/OSHA 300 log of work related injuries and illnesses, the Cal/OSHA 301 Injury Illness Incident Report, and corrective actions initiated to prevent recurrence. This information shall be considered the minimum elements required for a comprehensive incident report provided to OCTA.

D. A Serious Injury, Serious Incident, OSHA Recordable Injury/Illness, or a Significant Near Miss shall require a formal incident review at the discretion of the Authority's Project Manager. The incident review shall be conducted within seven (7) calendar days of the incident. This review shall require a company senior executive, company program or project manager from the Contractors' organization to participate and present the incident review as determined by the OCTA Project Manager. The serious incident presentation shall include action taken for the welfare of the injured, a status report of the injured, causation factors that lead to the incident, a root cause analysis (using 5 whys and fishbone methods), and a detailed recovery plan that identifies corrective actions to prevent a similar incident, and actions to enhance safety awareness.

1. Serious Injury: includes an injury or illness to one or more employees, occurring in a place of employment or in connection with any employment, which requires inpatient hospitalization for a period in excess of twenty-four hours for other than medical observation, or in which an employee suffers the loss of any member of the body, or suffers any serious degree of physical disfigurement. A serious injury also includes a lost workday or reassignment or restricted injury case as determined by the Physician's first report of injury or Cal/OSHA definitions.

2. Serious Incident: includes but not limited to property damage of $500.00 or more, an incident requiring emergency services (local fire, paramedics and ambulance response), news media or OCTA media relations response, and/or incidents involving other agencies (Cal/OSHA, EPA, AQMD, DTSC, Metrolink, FTA, FRA etc.) notification or representation.

3. OSHA Recordable Injury / Illness: includes and injury / illness resulting in medical treatment beyond First Aid, an injury / illness which requires restricted duty, or an injury / illness resulting in days away from work.

4. Significant Near Miss Incident; includes incidents where no property was damaged and no personal injury sustained, but where, given a slight shift in time or position, damage and/or injury easily could have occurred.

1.4 PERSONAL PROTECTIVE EQUIPMENT

Contractors, and all associated subcontractors, vendors and suppliers are required to provide their own personal protective equipment (PPE), including eye, head, foot, and hand protection, respirators, reflective safety vests, and all other PPE required to perform their work safely on Authority projects.

1.5 LANGUAGE REQUIREMENTS

The Contractor for safety reasons shall ensure employees that do not read, or understand English, shall have a bilingual supervisor or foreman when on the Authority property or projects.

1.6 WARNING SIGNS AND DEVICES

The Contractor shall provide signs, signals, and/or warning devices to be visible when and where a hazard exists. Signs, signals, and/or warning devices shall be removed when the hazard no longer exists.

1.7 REFERENCES

A. CCR Title 8 Standards (Cal/OSHA)
B. FCR Including 1910 and 1926 Standards
C. NFPA, NEC, ANSI, NIOSH Standards
D. Construction Industry Institute (CII)
E. Board of Certified Safety Professionals (BCSP)
F. OCTA Yard Safety Rules

END OF SECTION

EXHIBIT G: PROPOSAL EXCEPTIONS AND/OR DEVIATIONS

PROPOSAL EXCEPTIONS AND/OR DEVIATIONS

The following form shall be completed for each technical and/or contractual exception or deviation that is submitted by Offeror for review and consideration by Authority. The exception and/or deviation must be clearly stated along with the rationale for requesting the exception and/or deviation. If no technical or contractual exceptions or deviations are submitted as part of the original proposal, Offerors are deemed to have accepted Authority's technical requirements and contractual terms and conditions set forth in the Scope of Work (Exhibit A) and Proposed Agreement (Exhibit C). Offerors will not be allowed to submit this form or any contractual exceptions and/or deviation after the proposal submittal date identified in the RFP. Exceptions and/or deviations submitted after the proposal submittal date will not be reviewed by Authority.

Offeror:_____

RFP No.:_____ RFP Title: _____

Deviation or Exception No. : _____

Check one:

- Scope of Work (Technical) _____
- Proposed Agreement (Contractual) _____

Reference Section/Exhibit: _____ Page/Article No._____

Complete Description of Deviation or Exception:

_____
_____
_____
_____
_____
_____
_____
_____

Rationale for Requesting Deviation or Exception:

_____
_____
_____
_____
_____
_____

Area Below Reserved for Authority Use Only:

_____
_____