U.S. Department of Transportation
Office of the Secretary of Transportation
Office of Drug and Alcohol Policy and Compliance

DOT Oral Fluid Specimen

Collection Procedures Guidelines

About These Guidelines

These Guidelines are provided to you by the U.S. Department of Transportation (DOT) Office of Drug and Alcohol Policy and Compliance (ODAPC).

These Guidelines apply only to employers and individuals who come under the regulatory authority of the DOT, and those individuals who conduct oral fluid specimen collections under DOT regulations.

This document addresses and provides guidance concerning normal collection procedures and some of the more common problems or situations encountered. However, the information contained in this publication should not be interpreted or *viewed as adding to or modifying* the legal requirements of DOT's regulations.

The term "employee" is used throughout this document and has the same meaning as "donor" as used on the Federal Drug Testing Custody and Control Form (CCF). In addition, the terms "employee" and "donor" are used interchangeably in the document with no difference in meaning intended.

These Guidelines contain minimal graphics and formatting to ease transmission and downloading of the document from the Internet.

All information appearing in these Guidelines is in the public domain and may be used or reproduced without permission from DOT or others. Citation of the source is appreciated.

This document may be updated or modified based on additional interpretations or other procedural changes. To ensure collectors and service agents have the latest version, they should check the ODAPC website (http://www.transportation.gov/odapc) periodically and can also subscribe their email address to our list-serve at http://www.transportation.gov/odapc/get-odapc-email-updates.

[this space intentionally left blank]

INTRODUCTION

The DOT Agencies—Federal Aviation Administration (FAA), Federal Motor Carrier Safety Administration (FMCSA), Federal Railroad Administration (FRA), Federal Transit Administration (FTA), Pipeline and Hazardous Materials Safety Administration (PHMSA)—and United States Coast Guard (USCG) (now with the Dept. of Homeland Security) have issued regulations requiring anti-drug programs in the aviation, highway, railroad, transit, pipeline, and maritime industries. The DOT Agencies' rules require that employers conduct drug testing according to provisions of 49 CFR Part 40, "Procedures for Transportation Workplace Drug Testing Programs."

In collecting specimens in the DOT drug testing program, ***what counts most is doing it right, the first time and every time.***

Doing it right is important for protecting the safety of the traveling public. ***Doing it right*** is important to protect the integrity of the testing process. ***Doing it right*** is important to make sure that the process is fair to employees.

Doing it right means ***focusing on the details***. You have to understand and apply the specifics of each step in the collection process. You have to know how and when to fill out each item on the drug testing custody and control form. You have to get these details right consistently: no exceptions, no excuses.

As part of your training, you've already been introduced to the DOT's drug testing process rule, 49 CFR Part 40. Read it. The sections of Part 40 concerning the collection process (Subparts C, D, and E) are where to go to make sure you understand the details of the process, and to make sure that you are doing it right. When a question comes up, **Part 40 is the first place to go**.

This document provides additional information on how to get the details of the process right. It explains how Part 40 deals with each step of correct oral fluid specimen collections, and how to deal with issues that can come up in collections. It suggests best practices and helps to guide the collector through challenging scenarios. Keeping these Guidelines, as well as Part 40 itself, handy where you conduct collections is a good way of making sure you have the information you need.

Keeping other training materials available for review and refreshing your knowledge of the procedures can also help you do the job right on a consistent basis. Other training materials include the drug testing rules of the DOT Agencies (which tell you who is going to be tested and when), along with Part 40 Q&A's that provide guidance to Part 40. All can be found on the ODAPC website.

With the information you have available from DOT, including the rules and these Guidelines, you have what you need to do collections the right way every time a transportation employee comes to you for a test. **Collections are the first step, and a key step**, in making sure that we achieve the safety, integrity, and privacy goals of the program.

Thank you for taking the time and care to ***do it right the first time and every time***.

WHAT SHOULD COLLECTORS AND COLLECTION SITES KNOW ABOUT COLLECTING ORAL FLUID SPECIMENS?

On May 2, 2023, the DOT published in the Federal Register a final rule (effective June 1, 2023) [88 FR 27596] that authorized DOT-regulated employers to use oral fluid as an alternative to urine specimens for conducting DOT-required drug testing.

What you should know:

- Employers (not the employee) can choose the specimen type (urine or oral fluid) for the test reason (e.g., an employer can choose to have all pre-employment and random drug tests done via oral fluid and the other test reasons done via urine collections),
- Employers can choose the type of specimen collection for problem collections. For example:
  - 'shy bladder' or 'dry mouth',
  - direct observation collections per § 40.67 as directed by the DER,
  - employee brings materials to the collection site or employee conduct indicates an attempt to tamper with an oral fluid specimen,
- A best practice is for employers to have '**standing orders**' (e.g., written protocol) on when an oral fluid specimen is collected vs a urine specimen,
- An oral fluid specimen is considered a direct observation collection for all purposes of Part 40.

For each DOT-regulated employer for which you provide collections, you should:

- Be familiar with their '**standing orders**',
- Know which oral fluid collection device and laboratory the employer will be using,
- If you are collecting two different specimen types (urine and oral fluid), make sure you send the specimen to the correct laboratory, as not all laboratories will be conducting oral fluid testing, and some oral fluid testing laboratories may not be conducting urine testing.
- Have the DER's name and contact information.

As a collector or collection site, you should:

- Let each DOT-regulated employer you service know which specimen type you or your personnel are qualified to collect.
- If you are also providing urine collections, ensure you have the correct collection kits on hand and available for use.
- When switching from an oral fluid to a urine specimen collection, complete the oral fluid collection (including the CCF), then begin the urine specimen collection using a new CCF, and in the Remarks section of the CCF, document the reason for the changed collection process.

- As of the publication of these guidelines, there are no HHS-certified oral fluid testing laboratories with DOT-conforming devices.
- Therefore, no oral fluid specimens can be collected and tested for DOT-regulated employers.
- Only when there are two HHS-certified oral fluid testing laboratories with a DOT-conforming device, can oral fluid specimens be collected.
- DOT intends to publish a Federal Register document specifying the date the second oral fluid laboratory is certified by HHS, to clarify that oral fluid testing can be performed under Part 40.

- Note that a “neat” oral fluid is collected by expectoration (or spitting) into the undiluted device (a device with no liquid in the tubes).
- Note that a “buffer” oral fluid is collected using a device (with pads) and then diluted with a buffer preservation solution.

Things to look out for…

- **Ensure the oral fluid specimen you collected is sent to the correct laboratory listed on the CCF.**

- **Familiarize yourself with the employer's standing orders to know which collection method (oral fluid or urine) should be used in specific situations.**

- **Follow the manufacturer’s instructions on whether or not you can re-use a device.**

- **Always verify that you are using a device that is not expired.**

- **If you choose not to provide oral fluid collection services as a collection site, you should let your current DOT-regulated employers know about your business decision.**

TABLE OF CONTENTS

SECTION 1: THE ORAL FLUID COLLECTOR

What does a collector do?

A collector ***instructs and assists*** employees at a collection site, receives and makes an initial inspection of the specimen the employee provides, and initiates and completes the CCF.

Who can be an oral fluid collector?

Any person who has met each of the requirements in 49 CFR Part 40 (§ 40.35) can be an oral fluid collector, unless the person falls under an exception listed below (§ 40.31). Because Part 40 has specific procedures that need to be followed, everyone (including a medical professional (e.g., nurse, doctor, physician's assistant, or phlebotomist)) who acts as a collector in the DOT drug testing program is required to complete qualification training prior to collecting a specimen.

Who cannot be an oral fluid collector?

The following are situations that describe those individuals who may not or must not act as a collector (as specified in § 40.31):

- The **immediate supervisor** of a particular employee:
    - Must not act as the collector when that employee is tested unless no other collector is available, and only if the supervisor is permitted to do so under a DOT operating administration's drug and alcohol regulation.
- An **employee who is in a safety-sensitive position** and subject to the DOT drug testing rules:
    - Should not be a collector for co-workers in the same testing pool or who work together with that employee on a daily basis. This is to preclude any potential appearance of collusion or impropriety.
- An **individual working for a Department of Health and Human Services (HHS)-certified drug testing laboratory** (e.g., as a technician or accessioner):
    - Must not act as a collector if that individual can link the employee with the specimen drug test result or laboratory report.
- An **individual who is related to the employee (e.g., spouse, ex-spouse, or relative) or a close personal friend**. This requirement is to avoid a potential conflict of interest.

[this space intentionally left blank]

What are the training requirements under § 40.35?

To be permitted to act as an oral fluid collector in the DOT drug testing program, you must meet ***all*** the following requirements:

(1) Basic Information
(2) Qualification Training
(3) Initial Proficiency Demonstration
(4) Error Correction Training

(1) Basic Information

a) You must
   i. Be knowledgeable about and keep current on:
      1. 49 CFR Part 40,
      2. "DOT Oral Fluid Specimen Collection Procedures Guidelines," and
      3. DOT Agency regulations applicable to the employers for whom you perform collections,
   ii. Subscribe to the ODAPC list-serve at http://www.transportation.gov/odapc/get-odapc-email-updates

NOTE: For additional information on the DOT agency regulations, ***see Appendix E***.

(2) ***Qualification training***

You must receive qualification training that provides instruction on the following subjects:

a) Training on the testing procedures of Part 40.
b) Training to proficiency in the operation of the particular oral fluid collection device(s) you will be using for DOT-regulated collections;
c) All steps necessary to complete a collection correctly, and the proper completion and transmission of the CCF;
d) "Problem" collections (e.g., situations like "dry mouth" and attempts to tamper with a specimen);
e) Fatal flaws, correctable flaws, and how to correct problems in collections; and
f) Your 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.

(3) ***Initial Proficiency Demonstration***

Following the completion of your qualification training, you must demonstrate proficiency in collections by completing five consecutive error-free mock collections for **EACH DEVICE YOU WILL USE**. The five mock collections per device must include:

- One uneventful collection scenario,
- One insufficient 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.

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 you and attest in writing that the mock collections are "error-free."

A best practice is having a third person act as the donor so the trainee can experience "collecting from an employee." If only the monitor and the trainee are present, then the monitor should act as the donor by interacting meaningfully with the collector trainee, making sure the trainee gets the experience of both uneventful and problem collections.

The person who monitors the mock proficiency demonstrations must be a qualified oral fluid collector who has demonstrated necessary knowledge, skills, and abilities by having:

1) Regularly conducted DOT oral fluid drug test collections for a period of at least one year;
2) Conducted oral fluid collector training under Part 40 for at least one year*; or
3) Successfully completed an oral fluid "train the trainer" course.*

The monitor in the 2nd and 3rd categories above does not need to practice actively as an oral fluid collector as long as this person has met the collector qualification requirements.

*NOTE: Because HHS has not yet certified an oral fluid laboratory, we have amended the requirements to authorize individuals to monitor mock oral fluid collection without meeting the requirement of being a qualified oral fluid collector, as explained below.

On 11/5/2024, DOT published a final rule that provides temporary regulatory flexibility regarding who can monitor mock oral fluid collections (89 FR 87798). To be a monitor for oral fluid mock collections, you need not be a qualified oral fluid collector, but you either 1) have to conduct oral fluid collector training (the one-year requirement is being waived) or 2) successfully complete an oral fluid "train the training" course.

This regulatory flexibility is effective from 12/5/2024, the effective date of the November 5, 2024, final rule, until 1 year after HHS publishes a Federal Register notice of the first certified oral fluid drug testing laboratory. DOT will publish notice of the expiration date in the Federal Register.

NOTE: It is recommended that individuals arrange for both qualification training and initial proficiency demonstration training simultaneously. The entire training process should be completed within 30 days of the start date. If the student has not completed the device proficiency training within the 30-day timeframe, it is recommended he/she re-take the qualification training component of the program.

Error Correction Training

If you make a mistake in the collection process that causes an oral fluid test to be cancelled [i.e., a fatal flaw (§ 40.199) or an uncorrected correctable flaw (§ 40.203)] (see page 36 of these guidelines for a list of fatal flaws), you must undergo error correction training:

1) This training must occur within 30 days of the date you are notified of the error that led to the need for retraining.
   i. You may continue to perform DOT collections during this period. However, if you do not complete the error-correction training within 30 days, you are no longer qualified to conduct DOT collections.
2) This training covers only the subject matter area(s) in which the error that caused the test to be cancelled.
3) This training must be provided, and your proficiency must be documented, by a person who has the same qualifications as someone who can monitor mock proficiencies.
4) You must demonstrate your proficiency in the collection procedures of this part by completing three consecutive error-free mock collections using the device you used for the cancelled test:
   i. One uneventful scenario, and
   ii. Two scenarios related to the area(s) in which your error(s) occurred.
5) The person providing the training must monitor and evaluate your performance and attest in writing that the mock collections were "error-free."

REMINDER…If a laboratory rejects a specimen because you did not provide a signed statement for a 'correctable flaw', you will need to complete error correction training. Remember, ***do it right the first time and every time!***

How often does the collector need to re-qualify?

At least **every five years** from the date that you satisfactorily completed the qualification training and initial proficiency demonstration requirements, you must **complete refresher training.** The five-year mark begins from when you successfully completed the mock collections. This training must meet all of the same qualification training and initial proficiency demonstration requirements as when you initially became qualified.

What documentation does the collector need to show that they meet the qualifications?

As a collector, it's your responsibility to maintain documentation to show that you currently meet all of the qualification requirements. You are not required to keep this documentation with you, but you are required to provide this documentation on request to DOT representatives and employers and Consortium/Third-party administrators (C/TPAs) who may contract for your services. You are not required to provide any certification or other documentation regarding your training to the employee. See ***Appendix A*** for suggested training documentation.

On request, you should be prepared to provide sufficient detail on the content of the training and proficiency so that the Federal inspector can be confident that you fully met the requirements of the regulation. Training organizations should provide you with the required documentation for your training when you successfully complete the entire training course. For

example, you could present a training graduation certificate and/or letter signed by the qualified trainer/observer indicating you attended and successfully completed the course and completed the mock collections.

If you are leaving one organization for another, a good practice is to take copies of any documents related to your collector qualifications. If you are not able to demonstrate that you are qualified, you will need to complete the collector qualification training again.

What if the collector was originally trained using the paper copy of the CCF, and now they will be using the electronic CCF?

There are no separate training requirements for using an electronic CCF, but you should be familiar with how the electronic CCF program you will be using works.

Does DOT provide collector training?

No, DOT does not offer collector training or maintain a list of training programs or qualified trainers. DOT also does not approve, certify, or recommend the training programs of any organization or entity.

Collection sites may conduct their own training or solicit an outside organization or entity (e.g., professional training service) to conduct training. To find a training service, you may contact industry associations or organizations or search the internet (e.g., "DOT Collector Training").

Have additional questions about becoming an oral fluid collector?

If you have additional questions regarding collector qualification training, please read our *How Can I Become an Oral Fluid Collector for DOT Drug Testing?* document on the ODAPC website: http://www.transportation.gov/odapc/oral_fluid_collector.

SECTION 2: THE COLLECTION SITE

What is a collection site?

A collection site is a place ***selected by the employer*** where employees present themselves for the purpose of providing an oral fluid specimen for a DOT-required drug test.

The collection site may be:

1. A permanent or temporary facility located either at the work site or at a remote site; or
2. In a medical facility, a mobile facility (e.g., a van), a dedicated collection facility, or any other location meeting the requirements of § 40.47.

The collection site must have:

All the 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, as well as a suitable clean surface for writing.

SECTION 3: SECURING A COLLECTION SITE

How does the collector secure a collection site and other sites used for other purposes?

As the collector, **you are in charge** of authorized access at the collection site. You have the very important responsibility of maintaining collection site security and integrity. All collection sites must meet the requirement of § 40.48, including the following security requirements:

1. Procedures or restrictions to prevent unauthorized access to the site during the collection;
2. Procedures to prevent the employee or anyone else from gaining unauthorized access to the collection materials and specimens. You should also ensure that the employee does not have access to items that could be used to adulterate or dilute the specimen (e.g., mouthwash, mints, citric acid candy, or chewing gum);
3. Procedures to ensure the security of the facility during the collection process to maintain privacy to the employee and prevent you from being distracted;
4. Procedures to ensure that all authorized persons are under the supervision of a collector at all times when permitted into the site; and
5. Procedures to provide for the secure handling and storage of specimens.

If the collection site uses a facility normally used for other purposes before the collection is conducted, you must also ensure that:

1. Access to collection materials and specimens is effectively restricted;
2. Undetected access is not possible; and
3. The facility is secured against access during the procedure to ensure privacy to the employee and to prevent you from being distracted.
    a. Limited-access signs must be posted.

See "DOT's Steps to Oral Fluid Collection Site Security and Integrity" in ***Appendix B***.

Who can be at the collection site?

Only employees being tested, collectors, other collection site workers, DERs, employee and employer representatives authorized by the employer, and DOT representatives are authorized to be at the site. Unauthorized personnel include any individuals not specifically authorized by the regulation to be present at the collection site.

Only you and the employee (and, if necessary, a DOT representative) are allowed in the area where the employee provides an oral fluid specimen.

As the collector, you are in charge at the collection site, and allowing only authorized personnel in the collection site will minimize any disruptions to the collection process. Remember, ***do it right the first time and every time!***

SECTION 4: COLLECTION SUPPLIES

What are the collection supplies?

The following items must be available at the collection site to conduct proper collections:

A. A collection device meeting the requirements listed in ***Appendix C*** of these Guidelines.
B. Paper version of the CCFs or whatever is necessary for the approved electronic version of the CCF (electronic CCF) being used.

Recommended for use:

1. Single-use disposable gloves for use by collectors while conducting/handling specimens,
2. Access to water (e.g., 8 oz. sealed bottled water) for use in case of a "dry mouth" scenario,
3. Hand sanitizer, wipes, soap and water, or another means of cleaning one's hands before the collection. This could be necessary if an employee needs to separate the employee's cheek from the employee's gum to permit full inspection (§ 40.72(a)(1)).

How many CCFs and collection devices should the collector have at a collection site?

Ensure that you have the **correct and sufficient quantity of supplies** to conduct a collection. Be sure to check your supplies and the expiration dates on the devices **before** heading out to a collection site or at the beginning of your workday. ***Do it right the first time and every time!***

As a best practice, ***double/triple up on your supplies*** in the event a second CCF or collection device is required for each employee (e.g., situations like "dry mouth").

When using an electronic CCF, you should have a supply of paper CCFs in the event you are not able to complete the electronic CCF due to technical issues (e.g., power failure, device failure, etc.).

> Make sure you are familiar with the employer's "standing orders" regarding oral fluid vs. urine collections.
>
> Remember, if the employer requires it, you may need to switch to a urine specimen collection (using a new CCF) to complete the collection.
>
> If you are also a qualified urine collector, you should always bring some urine kits to the collection in the event you need to switch to a urine specimen collection.

SECTION 5: FEDERAL DRUG TESTING CUSTODY AND CONTROL FORM

When is a CCF Used?

The CCF must be used to document every oral fluid specimen collection required by the DOT drug testing program. You must not use a non-Federal form or an expired CCF to conduct a DOT collection.

In what format is the CCF?

The CCF can be either a five-part carbonless manifold paper form, an electronic version of the paper form, or a combination paper and electronic format. In either case, it must consist of the following copies:

Copy 1. Test Facility	- sent to the laboratory with the specimen
Copy 2. Medical Review Officer	- sent to the MRO
Copy 3. Collector	- retained by the collector
Copy 4. Employer	- sent to the employer
Copy 5. Employee	- given to the employee

To view what the form looks like, you can find it on the DOT's website (https://www.transportation.gov/odapc/oral_fluid_collector) or on the Department of Health and Human Services (HHS) website (https://www.samhsa.gov/substance-use/drug-free-workplace)

Paper CCFs are available from a number of different sources (e.g., laboratories and service agents), although they are usually provided by a laboratory.

Can the collector use an electronic version of the paper CCF?

You may use an electronic CCF if the laboratory's electronic CCF system has been approved through the HHS National Laboratory Certification Program, and the employer has chosen to use an electronic CCF. SAMHSA maintains the list of HHS-certified test facilities (laboratories) approved to use an electronic CCF on its website: https://www.samhsa.gov/substance-use/drug-free-workplace.

Is the collection process any different when the collector uses an electronic CCF?

No, nothing changes in the collection process. When you use an electronic CCF, you will still collect and document the same information as you would when using the paper version of the CCF. The only difference is how you document the information (in an electronic format) and the medium in which you distribute the form (e.g., electronically).

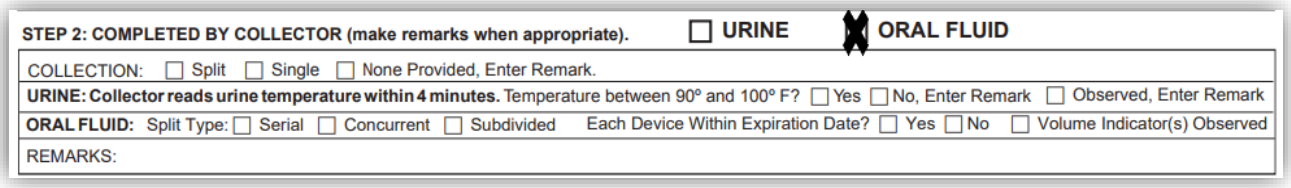
For a combination of electronic and paper CCF that has been signed by the collector and employee using electronic signatures, the collector should send the "authoritative copy" (i.e., printout of Copy 1 of the electronic CCF with the specimen. If there is a problem with printing the authoritative copy (e.g., a printer error), the collector should sign the reprinted Copy 1 (in the presence of the donor) using a wet-ink signature in Step 4 to designate this copy as the single authoritative copy and document what the issue was in the Remarks section. Remember—***do it right the first time and every time!***

When using an electronic CCF, does the collector need to implement any security/confidentiality measures?

Yes. Just as with the paper CCF, 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.

Is there a different CCF for conducting a urine vs an oral fluid specimen collection?

No. In Step 2 of the CCF, you need to indicate which specimen you are collecting.


STEP 2: COMPLETED BY COLLECTOR (make remarks when appropriate). ☐ URINE ☒ ORAL FLUID

COLLECTION: ☐ Split ☐ Single ☐ None Provided, Enter Remark.

URINE: Collector reads urine temperature within 4 minutes. Temperature between 90° and 100° F? ☐ Yes ☐ No, Enter Remark ☐ Observed, Enter Remark

ORAL FLUID: Split Type: ☐ Serial ☐ Concurrent ☐ Subdivided Each Device Within Expiration Date? ☐ Yes ☐ No ☐ Volume Indicator(s) Observed

REMARKS:

[this space intentionally left blank]

SECTION 6: INFORMATION EMPLOYERS PROVIDE TO COLLECTORS

As required in § 40.14, an employer or its service agent—for example, a C/TPA—must ensure you have the following information when you are conducting an oral fluid specimen collection for that employer:

1. Full name of the employee being tested.
2. Employee SSN or ID number.
    a. Drivers tested under the authority of the FMCSA need to provide their Commercial Driver's License (CDL) Number and State of issuance (see § 40.3).
3. Laboratory name and address (can be pre-printed on the CCF).
4. Employer name, address, telephone number, and fax number (this can be pre-printed on the CCF at Step 1-A).
5. Designated Employer Representative (DER) name and telephone number.
6. Medical Review Officer (MRO) name, address, telephone number, and fax number (can be pre-printed on the CCF at Step 1-B).
    a. The MRO address cannot be a PO Box.
7. The DOT Agency that regulates the employee's safety-sensitive duties.
8. Test reason, as appropriate: Pre-employment; Random; Reasonable Suspicion/Reasonable Cause; Post-Accident; Return-to-Duty; or Follow-up. The checkmark can be pre-printed in the appropriate box on the CCF at Step 1-E. For DOT (FRA, FAA, FMCSA, PHMSA, FTA) tests, you would NEVER check the "other" test reason box.
9. Collection site address and the collector's telephone number (must not be a call center number) (see § 40.40(c)(4)).
    a. The collector's phone number on the CCF must be the number to directly reach the individual collector and/or the collector's supervisor and not a corporate "toll-free" number to a call center.
10. (Optional) C/TPA name, address, telephone number, and fax number (can be pre-printed on the CCF).
11. Specimen type to be collected (i.e., oral fluid or urine).

As a collector, if the employer has not provided you with this information, as a best practice contact the employer (or C/TPA if applicable) to obtain this information.

Is the employer required to provide the collector with the name and telephone number of the DER?

Yes! The employer must provide you with the name and telephone number of the appropriate DER (and C/TPA, where applicable). This is important information, and you must have it. If an employer has not provided you with that information, make every effort to get it.

Why? **You need a point of contact** regarding any problems or issues that may arise during the collection process (e.g., refusal to test at the collection site, an employee without a photo ID, etc.), including whether to perform a urine collection.

If an employer requires "after-hours" collections, you should have the DER's [or, when applicable, the C/TPA] "after-hours" **contact information** so you can contact them when necessary.

SECTION 7: IDENTIFYING THE EMPLOYEE

When does the collector verify the employee's identity?

As required in § 40.61, the employee must provide appropriate identification (ID) to you before the collection process commences.

Why do I do this? You want to ensure that the person from whom you're collecting the specimen is the same person sent by the employer for the test. You should check the employee's photo ID even if the employee already showed it to the receptionist when they checked in. Again, ***do it right the first time and every time!***

What type of employee ID is acceptable?

Acceptable forms of ID include:

1. A photo ID (e.g., driver's license, employee badge issued by the employer (other than in the case of an owner-operator or other self-employed individual), passport, or any other picture ID issued by a Federal, state, or local government agency).
    a. A collector may accept an expired photo ID issued by a Federal, state, or local government agency, but the ID should not be expired for more than 1 year.
    b. A digital driver's license or other digital ID should not be accepted for the purposes of identifying a donor for a collection under 49 CFR Part 40.
2. Identification by an employer or employer representative, or
3. Any other identification allowed under an operating administration's rules.

If the employee does not have an acceptable ID, you must contact the DER to verify the identity of the employee. The collection should not proceed until positive identification is obtained.

Unacceptable forms of ID include:

1. Identification by a co-worker,
2. Identification by another employee being tested,
3. Use of a non-photo ID card (e.g., social security card, credit card, union or other membership cards, pay vouchers, or voter registration card), or
4. Faxed or photocopies of ID documents.

Is the collector required to have an ID?

You must have appropriate ID that includes your name and the name of your employer. If the employee asks for you to provide ID, show the employee your ID. There is no requirement for you to have a picture ID or an ID with your home address or telephone number.

SECTION 8: ORAL FLUID COLLECTION PROCEDURES

What does the collector do before each collection?

As the collector, you should do as much as possible to **deter potential tampering, adulteration, or substitution of the specimen.**

Why am I Doing This? You are creating an environment to **minimize the employee's opportunity to try to beat the test by tampering with, adulterating, or substituting** their specimen. You don't want the employee to bring anything into the collection site, use anything located at the collection site, or have something given to them while at the collection site. Remember, ***do it right the first time and every time***!

How does the collector start the collection?

After properly securing the collection site and having all collection supplies available, as required by Part 40 and described in Sections 2, 3, 4, and 5 above, **start the collection without undue delay** after the employee arrives at the collection site.

Do not delay the collection because the employee is not ready or states that they are unable to provide a specimen (see § 40.61). In most cases, employees who state they cannot provide a specimen will, in fact, provide sufficient quantity to complete the testing process. If an alcohol breath test is also scheduled, the alcohol test should be conducted first, if practicable, though the rule (§ 40.61(b)(1)) example suggests some situations where there can be an exception to this normal process.

Request the employee to present an acceptable form of ID [***see Section 7*** of these Guidelines].

If the employee cannot produce a positive ID, you must contact the DER to verify the identity of the employee [***see Section 7*** of these Guidelines].

When using the paper CCF, you must explain the basic collection procedures to the employee and notify the employee that instructions for completing the CCF can be found at the HHS (https://www.samhsa.gov/substance-use/drug-free-workplace) and DOT (https://www.transportation.gov/odapc) websites (see § 40.61).

When using the electronic CCF, you must explain the basic collection procedures to the employee and show the employee the instructions by either providing the employee with a paper copy of the instructions or have the employee view the instructions on the media you are using to complete the electronic CCF (See § 40.61).

Does the collector require the employee to remove outer clothing?

Yes. As specified in §40.61, direct the employee to remove any unnecessary outer clothing (e.g., coat, jacket, hat, etc.) and to leave any briefcase, purse, or other personal belongings the employee is carrying with the outer clothing. The employee may retain his or her wallet. If the employee asks for a receipt for any belongings left with the collector, you must provide one.

Why am I doing this? Some employees will try to beat the test. The purpose of having the employee remove any outer clothing and not take any personal belongings into the collection site is to **prevent the employee from bringing in items to try to beat the test.** Remember, ***do it right the first time and every time****!*

To safeguard the employee's belongings, you may establish procedures to place their belongings in a locked space (at the collection site) or develop other alternate methods to secure the belongings. For example, if an employee comes to the collection site with his or her medication and wants you to secure it, you may place the medication in a locked cabinet, if available. Alternatively, you could seal the medication in an envelope, secure the envelope with tamper-evident tape, and retain the envelope in a secure place.

You may encourage the employee to leave any other items that they will not need during the collection, along with their other belongings.

Is the employee required to empty all the employee's pockets?

Yes. You must **direct the employee to empty all the employee's pockets** and display the items to ensure that no items are present that could be used to adulterate the specimen. Remember, ***do it right the first time and every time!*** If nothing is there that can be used to adulterate a specimen, the employee places the items back into the pockets and the collection procedure continues. If the employee refuses to empty the employee's pockets, this is considered a refusal to cooperate in the testing process [***see Section 10*** of these Guidelines].

Why am I doing this? The purpose of having the employee empty ***ALL*** the employee's pockets is for you to verify that the employee did not bring any items to the collection site to try to beat the test.

What do I do with items an employee brings to the collection site?

If you observe materials brought to the collection site (e.g., a commercial drug culture product, a collection device, pad, or stick that mimics that to be used for an oral fluid collection), or the employee's conduct clearly indicates an attempt to adulterate, substitute, or alter the specimen, you must stop the collection and report the circumstances to the DER so that the employer can decide whether to deem the situation a refusal. Items that were found should be fully described in an attached memorandum for record, copies of which should be sent to the MRO and the employer along with the completed CCF ***[see Section 10*** of these Guidelines].

If the item that could be used to adulterate/substitute the specimen (e.g., common personal care products such as mouthwash, lozenges, capsules, breath mints, or breath spray) appears to have been brought inadvertently to the collection site, secure it, and proceed with the collection. Whatever the employee brings to the collection site, the collector should return it to the employee at the end of the collection (see § 40.61).

What steps does the collector take before the employee provides an oral fluid specimen? (§ 40.72)

You will request the employee to open their mouth and inspect the oral cavity to ensure it is free of any items that could impede or interfere with the collection.

- You may need to ask the employee to lift the employee's tongue and/or separate the cheek from the employee's gum.
    - Dental appliances (e.g., a retainer or aligners) are not required to be removed.
    - You may use a flashlight to help you inspect the oral cavity of the employee.
    - If the employee is asked to separate the cheek from the employee's gum, the employee may cleanse his or her hands.

- If the employee claims that they have a medical condition that prevents opening their mouth for inspection, follow the procedure described in § 40.193(a) [***see Section 9*** of these Guidelines].

- If you observe materials brought to the collection site, or the employee's conduct clearly indicates an attempt to adulterate, substitute, or alter the specimen, you must stop the collection and report the circumstances to the DER so the employer can decide whether to deem the situation a refusal [***see Section 10*** of these Guidelines].

- If an item (e.g., candy, gum, food, or tobacco) is present that might impede or interfere with the collection, you must request the employee to remove the item.
    - If the employee removes the item, you must give the employee water, up to 8 oz., to rinse the employee's mouth. The employee may drink the water. You would then start a 10-minute wait period before beginning the collection.
    - If the employee refuses to remove the item or rinse, you must stop the collection and report the information to the DER so the employer can decide whether to deem the situation a refusal [***see Section 10*** of these Guidelines].

- If the employee's saliva is abnormally colored or if the employee claims to have "dry mouth," give the employee water, up to 8 oz., to rinse the employee's mouth. The employee may drink the water.
    - If the employee refuses to rinse the employee's mouth, you must stop the collection and report the information to the DER so that the employer can decide whether to deem the situation a refusal [***see Section 10*** of these Guidelines].

- If there is nothing of concern in the oral cavity and no "dry mouth" condition exists, you must start the 10-minute wait period before collecting a specimen.

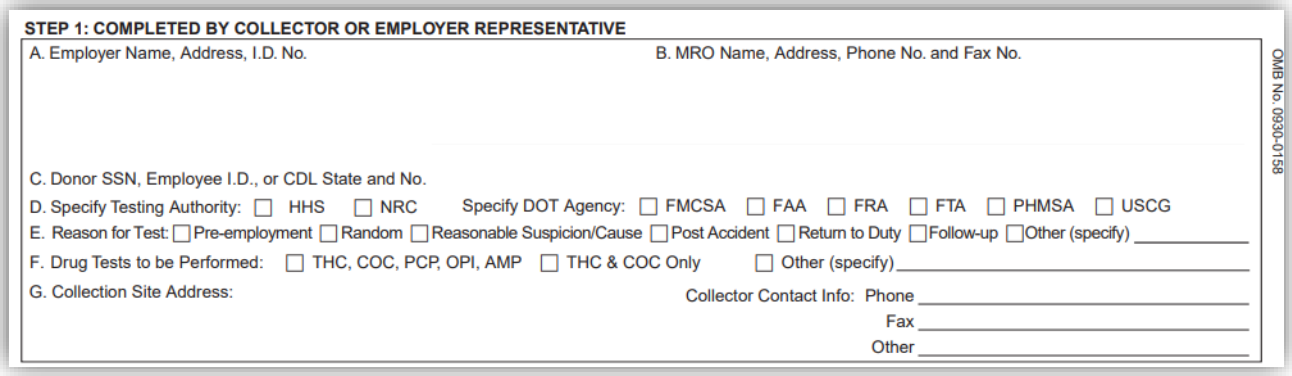
What occurs during the 10-minute wait period?

You will need to review the procedures required for a successful oral fluid specimen collection with the employee, as stated in the manufacturer's instructions for the specimen collection device that will be used.

Ensure and verify that the information in Step 1 is complete and accurate.

Also, you should:

Ensure and verify that the laboratory name and address and a pre-printed specimen ID number are provided at the top of the CCF. Double-check that the pre-printed specimen ID number at the top of the form matches the specimen ID number on the labels/seals at the bottom of the form.


STEP 1: COMPLETED BY COLLECTOR OR EMPLOYER REPRESENTATIVE

A. Employer Name, Address, I.D. No.

B. MRO Name, Address, Phone No. and Fax No.

OMB No. 0930-0158

C. Donor SSN, Employee I.D., or CDL State and No.

D. Specify Testing Authority: ☐ HHS ☐ NRC Specify DOT Agency: ☐ FMCSA ☐ FAA ☐ FRA ☐ FTA ☐ PHMSA ☐ USCG

E. Reason for Test: ☐ Pre-employment ☐ Random ☐ Reasonable Suspicion/Cause ☐ Post Accident ☐ Return to Duty ☐ Follow-up ☐ Other (specify) _____

F. Drug Tests to be Performed: ☐ THC, COC, PCP, OPI, AMP ☐ THC & COC Only ☐ Other (specify) _____

G. Collection Site Address:

Collector Contact Info: Phone _____

Fax _____

Other _____

If the following information is not already preprinted on the CCF, or prefilled on the electronic CCF, begin entering the required information in Step 1 (see § 40.40):

- **Step 1A:** ***Employer's name, address, telephone and fax number, and I.D. number*** (if applicable)
  - An employer must provide you the name and telephone number of the appropriate DER. This may be part of the CCF information that is pre-printed or may be separately documented. If there is no employer or DER telephone number on the CCF, then you should write in the DER name and telephone number on the CCF (if this information is available) so that either you or the MRO may get in touch with a company representative when any problems arise related to that specimen.
    - Employer's fax number can be included but is not required.

- **Step 1B:** ***MRO name, address, telephone, and fax number***
  - Part 40 requires a specific MRO's name and address on the CCF rather than the name of the clinic or medical facility (the MRO address must contain at least a number and street address—a PO Box can be included, but not in lieu of the number and street address).
    - MRO's fax number can be included but is not required.

- **Step 1C:** ***Employee SSN, employee ID number, or CDL State and Number***
  - This can be the individual's actual Social Security Number, a unique identifier issued by the employer, a State-issued driver's license number (including a CDL), or any other State-issued or Federally-issued identification number.
    - Drivers tested under the authority of FMCSA need to provide their Commercial Driver's License (CDL) Number and State of issuance.
  - If the employee does not provide this identifying information, it is not a refusal to test but requires the collector to annotate this in the Remarks section.

- **Step 1 D:** ***Testing Authority***
  - Check the applicable DOT Agency: FMCSA, FAA, FRA, FTA, PHMSA, or USCG.
    - The CCF may be pre-printed with the DOT Agency designation box already checked. If it is not, the employer must ensure you have this information.

- **Step 1E:** ***Reason for test***
  - Pre-employment, Random, Reasonable Suspicion /Cause, Post-Accident, Return-to-Duty, or Follow-up.
    - "Other" is only checked when it is a USCG Periodic test.

- **Step 1F:** ***Drug test to be performed***
  - Check the box for "THC, COC, PCP, OPI, AMP"

- **Step 1G:** ***Collection site information***
  - You must provide information to identify the site where the collection takes place (e.g., street address, city, state, zip code, telephone number, and fax number) that can be used to reach the collector and/or the collector's supervisor. Remember that a call center number is never to be entered here [***see Section 14:*** Question #5].

How does the employee receive a collection device?

You decide who selects the collection device. You can select it yourself or have the employee select one from the available supply. With both you and the employee present, either you or the employee then unwraps or breaks the seal of the collection device. (It is best practice for you to do this since you may be able to break the seals more efficiently.)

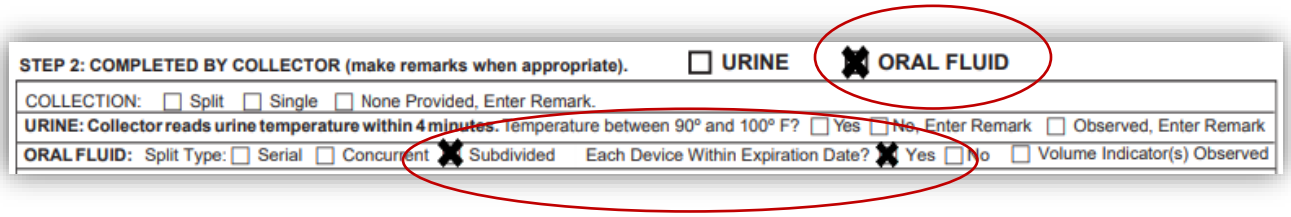
Is it okay to use an expired collection device?

No. After the collection device has been selected, you must check the expiration date on the specimen bottles that are to be sent to the laboratory and show it to the employee. **If the device has expired, you must not use it.** Remember—***do it right the first time and every time!***

You will need to document the type of collection and the expiration date of the device on the CCF.

- **Step 2:** ***Completed by Collector***
  - Check "Oral Fluid" as the type of collection
  - For "Oral Fluid" split type, check the box for "Subdivided"

- Check the box after ensuring each device is within its expiration date.


STEP 2: COMPLETED BY COLLECTOR (make remarks when appropriate). ☐ URINE ☒ ORAL FLUID

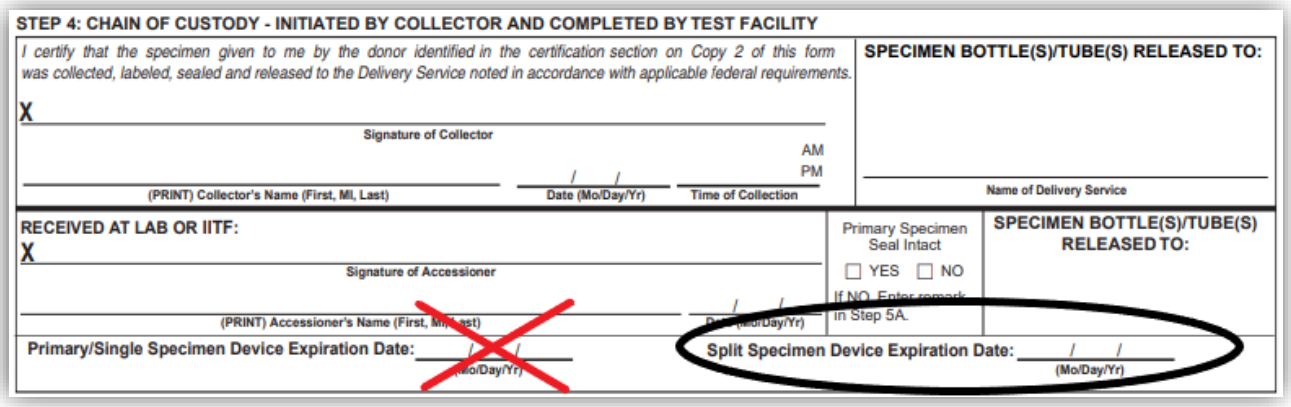
COLLECTION: ☐ Split ☐ Single ☐ None Provided, Enter Remark.

URINE: Collector reads urine temperature within 4 minutes. Temperature between 90° and 100° F? ☐ Yes ☐ No, Enter Remark ☐ Observed, Enter Remark

ORAL FLUID: Split Type: ☐ Serial ☐ Concurrent ☒ Subdivided Each Device Within Expiration Date? ☒ Yes ☐ No ☐ Volume Indicator(s) Observed

Because an oral fluid specimen is considered a directly observed collection for all purposes of Part 40, in Step 2 of the CCF, 1) you do not need to check the "Observed" box, and 2) you do not need to provide the observer's name in the REMARKS section.

- **<u>Step 4:</u>** ***Completed by Collector***
  - Enter the **Split Specimen Device Expiration Date**.
    - Because you are using one oral fluid device to collect a single specimen, which is then subdivided in the presence of the donor, only one entry in Step 4 is needed. Enter the device expiration date next to the text "Split Specimen Device Expiration Date" on COPY 1—Test Facility Copy ONLY
      - You will need to lift Copy 1 of the CCF so that copies 2–5 are not underneath it, then enter the expiration date so it does not transpose onto Copies 2–5. You will complete the rest of the collector portion in Step 4 of the CCF once the collection process is completed.


STEP 4: CHAIN OF CUSTODY - INITIATED BY COLLECTOR AND COMPLETED BY TEST FACILITY

I certify that the specimen given to me by the donor identified in the certification section on Copy 2 of this form was collected, labeled, sealed and released to the Delivery Service noted in accordance with applicable federal requirements.

X _____ Signature of Collector

_____ (PRINT) Collector's Name (First, MI, Last) ___/___/___ Date (Mo/Day/Yr) _____ AM PM Time of Collection

SPECIMEN BOTTLE(S)/TUBE(S) RELEASED TO:

_____ Name of Delivery Service

RECEIVED AT LAB OR IITF:

X _____ Signature of Accessioner

_____ (PRINT) Accessioner's Name (First, MI, Last) ___/___/___ Date (Mo/Day/Yr)

Primary Specimen Seal Intact ☐ YES ☐ NO If NO, Enter remark in Step 5A.

SPECIMEN BOTTLE(S)/TUBE(S) RELEASED TO:

Primary/Single Specimen Device Expiration Date: ___/___/___ (Mo/Day/Yr)

Split Specimen Device Expiration Date: ___/___/___ (Mo/Day/Yr)

*****DO NOT USE AN EXPIRED DEVICE*****

To the greatest extent possible, keep the employee's unwrapped collection device within view of both you and the employee between the time that either you or the employee breaks the seal of the collection device until the specimen container is sealed.

Is the employee required to wash his or her hands?

Yes. You must instruct the employee to (1) use hand sanitizer, or (2) wash and dry his or her hands. The employee must not be allowed any further access to water or other materials that could be put into the specimen.

If the employee refuses to wash his or her hands—after being directed to do so—this is a refusal to cooperate in the testing process and you must stop the collection and immediately notify the DER/Employer of the refusal event so the employer can make the refusal determination [***see Section 10*** of these Guidelines].

After the 10-minute wait period, you will collect a specimen in accordance with the manufacturer's instructions for the collection device.

What procedures does the collector follow to collect and inspect the specimen?

Follow the manufacturer's instructions for completing the collection (e.g., inserting the pad into the specimen tube and capping the specimen tube). Carefully handle all open tubes containing diluent. If any diluent is spilled (i.e., before or after combining with the collected oral fluid), the collector should recollect the specimen using a new device.

According to § 40.73, as the collector, you must ensure the collection is performed correctly, the collection device is working properly, and a sufficient specimen volume is collected. Both you and the employee need to maintain visual contact of the specimen, to the greatest extent possible, until the labels/seals are placed over the caps/lids of specimen bottles A and B (see § 40.82). If you detect any conduct that clearly indicates an attempt to tamper with a specimen, you must stop the collection and report the information to the DER so that the employer can decide whether to deem the situation a refusal. Remember, you must note any unusual behavior or appearance of the employee on the CCF.

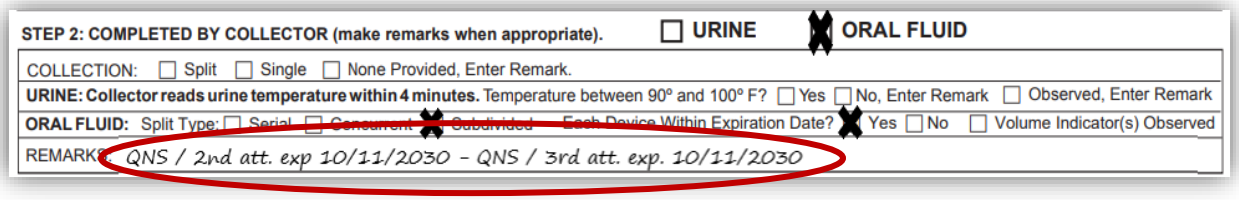
If an employee tells you, at the beginning of the collection process, that they cannot provide a specimen, you must still begin the collection procedure regardless of the reason given. You should tell the employee that most individuals can provide 2 mL of oral fluid, even when they think they cannot, and direct the employee to follow the manufacturer's instructions for the device and attempt to collect a specimen. If the employee states they could provide a specimen after drinking some fluids, urge the employee to drink (up to 8 ounces). Wait 10 minutes before beginning the next specimen collection. If the employee does not drink fluids, there is no need for an additional 10-minute wait period. Remember, ***do it right the first time and every time!***

Under your supervision, the employee is responsible for positioning the specimen collection device for collection. You should verify the position of the device and provide further instructions as needed. The device must be used according to the manufacturer's instructions for the specified time or until a sufficient volume of oral fluid has been collected, as shown by the device volume indicator or by the volume markings on the specimen tubes. For devices without a diluent (i.e., neat oral fluid specimens), inspect the volume markings on the specimen tubes after the specimen is collected to verify that at least 1 mL of oral fluid was collected (i.e., excluding any foam or bubbles above the oral fluid).

If the employee demonstrates their inability to provide a sufficient specimen according to the timeframe in the manufacturer's instructions, the collector **must provide another opportunity for the employee to do so**. (see § 40.193(a)).

- If there is a failure to collect a sufficient specimen, you must start the process again [see **page 18** within this Section of these Guidelines], follow the manufacturer's instructions on whether to use a new specimen collection device and note the failed collection attempt on the CCF.

Note: As the collector, when you provide the employee with another opportunity to collect a specimen and use a new device, the expiration date of that new device must be documented in the REMARK section on the CCF even if the expiration date is the same on each device.


STEP 2: COMPLETED BY COLLECTOR (make remarks when appropriate). ☐ URINE ☒ ORAL FLUID

COLLECTION: ☐ Split ☐ Single ☐ None Provided, Enter Remark.

URINE: Collector reads urine temperature within 4 minutes. Temperature between 90° and 100° F? ☐ Yes ☐ No, Enter Remark ☐ Observed, Enter Remark

ORAL FLUID: Split Type: ☐ Serial ☐ Concurrent ☒ Subdivided Each Device Within Expiration Date? ☒ Yes ☐ No ☐ Volume Indicator(s) Observed

REMARKS: QNS / 2nd att. exp 10/11/2030 - QNS / 3rd att. exp. 10/11/2030

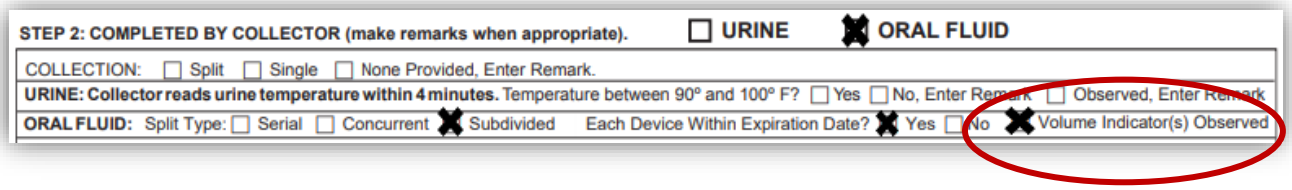
After collecting the oral fluid specimen, you must:

(1) Check the amount of oral fluid provided and
(2) Inspect the specimen for adulteration or substitution.

(1) Check the amount of oral fluid provided.

Make sure the specimen contains a sufficient amount of oral fluid as indicated by or on the device.

a. ***<u>If the device indicates the volume is sufficient</u>***, in Step 2 check the "Volume Indicator(s) Observed" box indicating that a sufficient specimen was collected.


STEP 2: COMPLETED BY COLLECTOR (make remarks when appropriate). ☐ URINE ☒ ORAL FLUID

COLLECTION: ☐ Split ☐ Single ☐ None Provided, Enter Remark.

URINE: Collector reads urine temperature within 4 minutes. Temperature between 90° and 100° F? ☐ Yes ☐ No, Enter Remark ☐ Observed, Enter Remark

ORAL FLUID: Split Type: ☐ Serial ☐ Concurrent ☒ Subdivided Each Device Within Expiration Date? ☒ Yes ☐ No ☒ Volume Indicator(s) Observed

b. ***<u>If the device indicates the volume is insufficient</u>*** :
   i. Discard the specimen;
   ii. Note the fact (which should include the time) of the insufficient specimen in the "Remarks" section; and
   iii. Immediately begin the "dry mouth process" after the 2nd attempt [***see Section 9*** of these Guidelines].

(2) Inspect the specimen for signs of tampering and adulteration

a. Check for unusual color, presence of foreign objects or material, or other signs of tampering or adulteration. (see § 40.73)

b. If it is apparent from this inspection that the employee has adulterated or substituted the specimen (e.g., abnormal color, foreign material, evidence of chewing on collection pad or stick), you must:

i. Complete the collection process for the suspect specimen and document the unusual characteristics in the Remarks section of the CCF as required by § 40.73;
ii. **Do not discard the suspect specimen**, but instead prepare the suspect specimen for shipment to the laboratory and
iii. **Immediately begin another collection in accordance with § 40.73.**

(Make sure to document in the remarks section that this is specimen 2 out of 2 and include the Specimen ID number of the other specimen. Make the same notation on the CCF of the suspect specimen (i.e., "specimen 1 out of 2")

c. If the employee provides a second oral fluid specimen, both the "first" [suspect specimen] and "second" specimens should be sent to the same oral fluid laboratory for testing.

If the employee refuses to provide a "second" specimen:

1. Note the facts in the "Remarks" Section in Step 2 of Copy 1;
2. Complete the CCF (including your printed and signed name in Step 4) and the employee's name in Step 5 of Copy 2);
3. Immediately report the facts to the employer;
4. Transmit the CCF copies to the appropriate parties (e.g., employer and MRO) and
5. **Discard any specimen** the employee previously provided.
6. The employer must decide whether the employee's actions constitute a refusal. *See Section 10* of these Guidelines.

What procedures does the collector follow to split and seal the specimen into the bottles?

Again, it's important that both you and the employee maintain visual contact with the specimen to the greatest extent possible until the labels/seals are placed over the specimen containers.

You, not the employee, must follow the manufacturer's instructions to package the split specimen collections. (see § 40.74)

You, not the employee, must then remove the tamper-evident seals from the CCF and place them on each bottle. The seal should be centered over the lid/cap and down the sides of the bottle to ensure that the lid/cap cannot be removed without destroying the seal. Do your best not to conceal the expiration date on the bottles with the tamper-evident seal. ***The employee must be present to observe the sealing of the specimen bottles***. (see § 40.74)

As with the paper CCF, if you are using an electronic CCF, you should make sure that the specimen ID on the bottle seals exactly matches the specimen ID on the electronic CCF. If they don't match, the lab will reject the specimen as having a fatal flaw (§ 40.199(b)(5)).

You, not the employee, write the date on the seals. You then request the employee to initial the seals. If the employee fails or refuses to initial the seals, you must note this in the "Remarks" line of the CCF and complete the collection process; this is not considered a refusal to test. (see § 40.74)

After the employee initials the seals on the bottles, it is best practice to check the seals to ensure they have not been inadvertently torn by the employee. If the seals are torn, ***see Section 14***, Question #12, for how to remedy the issue.

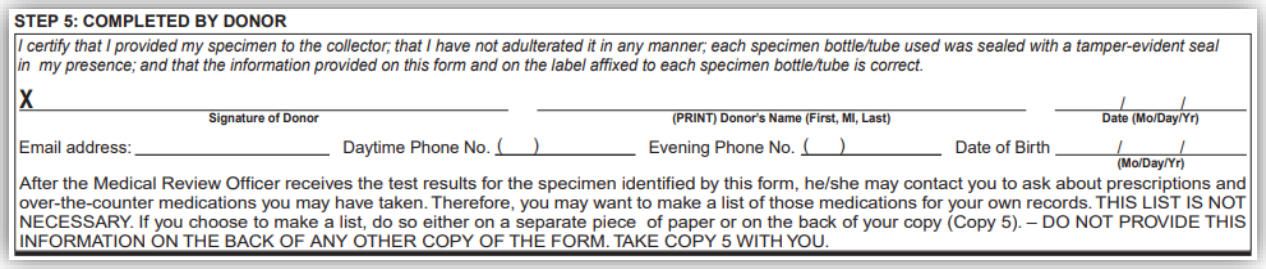
Note: You must not ask the employee to initial the labels/seals while they are still attached to the CCF; they must be initialed after they are placed on the bottles. Remember—***do it right the first time and every time!*** You should also inform the employee to use care during the initialing process to avoid damaging the labels/seals.

Since the specimen bottles are now sealed with tamper-evident tape and do not have to be under the employee's direct observation, if the employee desires to do so, they are allowed to wash their hands.

What step on the CCF does the employee now complete?

According to § 40.79, go to Copy 2 of the CCF and in Step 5, direct the employee to:

- Read the certification statement, then sign and print their name, and date; and
- Provide their day and evening contact telephone numbers, e-mail address, and date of birth.



STEP 5: COMPLETED BY DONOR

I certify that I provided my specimen to the collector; that I have not adulterated it in any manner; each specimen bottle/tube used was sealed with a tamper-evident seal in my presence; and that the information provided on this form and on the label affixed to each specimen bottle/tube is correct.

X _____ _____ ___/___/___

Signature of Donor (PRINT) Donor's Name (First, MI, Last) Date (Mo/Day/Yr)

Email address: _____ Daytime Phone No. (___)_____ Evening Phone No. (___)_____ Date of Birth ___/___/___ (Mo/Day/Yr)

After the Medical Review Officer receives the test results for the specimen identified by this form, he/she may contact you to ask about prescriptions and over-the-counter medications you may have taken. Therefore, you may want to make a list of those medications for your own records. THIS LIST IS NOT NECESSARY. If you choose to make a list, do so either on a separate piece of paper or on the back of your copy (Copy 5). – DO NOT PROVIDE THIS INFORMATION ON THE BACK OF ANY OTHER COPY OF THE FORM. TAKE COPY 5 WITH YOU.

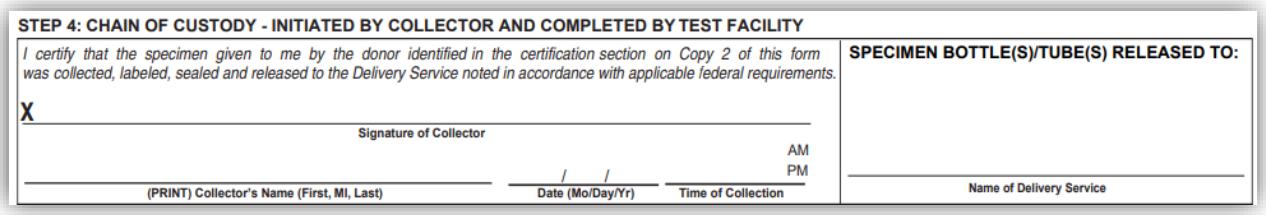
If the employee refuses to sign the form, or provide date of birth, printed name, e-mail address, or telephone numbers, you must make a notation on the "Remarks" line to that effect and complete the collection. This does not constitute a refusal to test. If the employee refuses to fill out any information, you must, as a minimum, print the employee's name in the appropriate place.

Before proceeding to the next step, you should double check that the employee completed all the fields in Step 5 of Copy 2. Remember, ***do it right the first time and every time!***

What step on the CCF does the collector now complete?

According to § 40.79, go back to Copy 1 and complete the collector's portion *in Step 4* by:

- printing your name (the name may be pre-printed);
- recording the date and time of the collection;
- signing your name where indicated; and
- entering the specific name of the delivery or courier service transferring the specimens to the laboratory.


STEP 4: CHAIN OF CUSTODY - INITIATED BY COLLECTOR AND COMPLETED BY TEST FACILITY

I certify that the specimen given to me by the donor identified in the certification section on Copy 2 of this form was collected, labeled, sealed and released to the Delivery Service noted in accordance with applicable federal requirements.

X

Signature of Collector

(PRINT) Collector's Name (First, MI, Last)

/ /

Date (Mo/Day/Yr)

AM PM

Time of Collection

SPECIMEN BOTTLE(S)/TUBE(S) RELEASED TO:

Name of Delivery Service

As a best business practice, double check the expiration date on Bottles A and B and ensure you have written the expiration date on the line in Step 4 marked "Split Specimen Device Expiration Date."

How does the collector package the specimen?

As required by § 40.79, you must ensure that all copies of the CCF are legible and complete. So, it's a good practice to **review all sections of the CCF before distributing any of the copies**. Once the copies are distributed, and the donor is no longer present, you cannot make any corrections/changes to the other copies (e.g., mark each device within the expiration date as "yes", etc.).

Why is this important? Making changes to other copies of the CCF after it has been distributed may bring your collection process into question. Remember, ***do it right the first time and every time!***

When using the paper CCF:

Once you are certain the paper CCF is properly completed in its entirety, remove Copy 5 of the CCF and give it to the employee.

Note: At this time, you can suggest to the employee that they list any prescription and over-the-counter medications they may be taking on the back of their copy of the CCF. This information may help the employee remember what medications they may have taken in the event the MRO calls to discuss a non-negative result.

Place the sealed specimen bottles and Copy 1 of the CCF inside the appropriate pouches of the leak-resistant plastic bag, and seal both pouches.

When using the Electronic CCF:

Ensure the electronic CCF is properly completed. Ask the employee if they want a paper or electronic copy of Copy 5. If the employee wants a paper copy, you should ensure that the copy you provide includes the same information that is contained on the front of Copy 5 of the

paper CCF. You should provide the paper copy of Copy 5 to the employee while the employee is still with you. As a best practice, make a notation that a paper copy of Copy 5 was given to the employee.

You may now advise employee that the collection process has been completed and that they may leave the collection site.

Place the sealed plastic bag in an appropriate shipping container (e.g., box or express courier mailer) designed to minimize the possibility of damage during shipment. If there are multiple collections, more than one sealed plastic bag can be placed into a single shipping container. Seal the shipping container as appropriate.

If a laboratory courier hand-delivers the specimens from the collection site to the laboratory, prepare the shipment as directed by the courier service. In this case, the plastic bag may not need to be placed into a shipping container, but the courier still needs to transport the bottles in a manner that protects them from damage.

If the laboratory courier does not hand-deliver the specimens to the laboratory but subsequently places the specimens into a commercial delivery system, you as the collector must place the specimens into a shipping container to minimize damage in transit.

After specimens are placed into shipping containers that are subsequently sealed, the shipping containers may be placed with other containers or packages that the collection site has waiting to be picked up by a courier.

Collection sites are expected to use reasonable security to ensure that their packages are secure and not subject to damage, theft, or other actions that could potentially raise questions related to the integrity of the specimens.

How and to whom does the collector distribute the remaining copies of the CCF?

Send Copy 2 of the CCF to the MRO and Copy 4 to the DER (or service agent if authorized by the employer). You must fax or otherwise transmit these copies to the MRO and DER within 24 hours or during the next business day. (see § 40.79)

The MRO copy (Copy 2) may be faxed to the MRO's secure fax machine, it may be scanned, and the image sent to the MRO's secure computer, or it may be mailed or sent by courier to the MRO. (It is recommended that the MRO copy be faxed since it is critical for the MRO to have this document to expeditiously conduct the verification process.)

In the case where the MRO copy (Copy 2) is faxed, or the scanned image is sent securely to the MRO, you or the collection site should maintain the MRO copy together with the collector's copies for 30 days.

Keep the collector copy (Copy 3) for at least 30 days, unless otherwise specified by applicable DOT operating administration's regulations.

Why am I doing this? Retaining Copy 3 is helpful in case the MRO's copy is lost in the mail or the faxed or scanned copy is not legible, and another copy is required by the MRO. The transmission process must be coordinated between the collection site and the MRO to ensure that transmission procedures meet the MRO's requirements and capabilities to receive the document (e.g., to receive secure faxes, MROs must provide secure fax numbers to collection sites, some MROs may want hard copies mailed, and others may want only faxed copies).

When is the specimen shipped to the laboratory?

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

If the specimen will not be shipped immediately, you are responsible for ensuring its integrity and security. Specimens in plastic bags that have not been placed into shipping containers or awaiting a laboratory courier should be kept in a secure location. Access to the specimens must be effectively restricted.

Note: Couriers, postal employees, and other personnel involved in transporting the sealed shipping container are not required to make, and should not attempt to make, additional chain of custody entries on the CCF.

The entire collection process is now complete.

[this space intentionally left blank]

SECTION 9: INSUFFICIENT QUANTITY OF ORAL FLUID

This is a situation when the employee does not provide a sufficient amount of oral fluid as indicated by the device (2 mL) for a DOT-required drug test.

This collection can be done using the same specimen type as the original collection (oral fluid), or this can be done by a collector qualified to use an alternate specimen collection (e.g., urine collection) in accordance with the employer's standing order. If there are no instructions from the employer, the DER must be contacted, and the collector needs to coordinate with the DER to make arrangements to complete the second specimen collection. This may include going to another collection site with qualified collectors to complete the collection process.

EXAMPLE:
Per the employer's standing order –

1. **Continue with an oral fluid collection:**
   a) If the employee states they could provide a specimen after drinking some fluids, urge the employee to drink (up to 8 ounces). Wait 10 minutes before beginning the next specimen collection.
   b) 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.
   c) A period of one hour must be provided or until the employer has provided a sufficient oral fluid specimen, whichever occurs first.

   The employee must remain at the collection site, in a monitored area designated by the collector, during the wait period.

2. **Change to an alternate specimen collection (i.e., urine)**:
   a) discard the insufficient specimen.
   b) discard the CCF for the insufficient specimen and begin a new CCF and make the proper notes in the remarks section of the new CCF; and
   c) begin the next collection under § 40.61(e) (for urine collections).

REMEMBER: Because a urine collection may be required, ensure a qualified urine collector is available. If no one is qualified to conduct the alternate collection, contact the employer so the employer can make arrangements at another collection site.

The employee is to be afforded ***a waiting period of up to one (1) hour*** from when they provided their insufficient specimen.

You and the collection site are to make every effort to ensure the employee is provided up to the full wait period [***see Section 14***: Question # 16]. The wait period must not extend beyond one (1) hour.

When does the one-hour wait period begin?

The one-hour wait period begins when the employee demonstrates their inability to provide a sufficient specimen after their second attempt.

What happens during the one-hour wait period?

You explain to the employee the process for a dry mouth collection and urge the employee to drink (up to 8 ounces) and wait an additional 10 minutes before beginning the next specimen collection.

- It is not a refusal to test if the employee declines to drink.
  - You should explain to the employee that not drinking sufficient fluids may result in the employee's inability to provide a sufficient specimen and would then require a medical evaluation.

Note: It is a best business practice, but it is not required, to know how many ounces of liquid are made available to an employee. For this reason, it is a good idea to provide the employee with a measured container (i.e., 8 ounces) instead of merely a water fountain.

You should be sensitive to how frequently you ask the employee to provide a specimen.

For example, asking the employee to provide a specimen frequently within the hour may not produce a sufficient specimen because that could accidentally interfere with the employee providing the required amount of specimen. A good practice would be to ask and not require the employee to make another attempt during the one (1) hour wait period. However, at the end of the one (1) hour wait period, the employee would be required to make an attempt.

Whether using a "Neat" or "Buffered" device follow the manufacturer's instructions on whether the device may be reused.

You should maintain a record in the "Remarks" line on the CCF of the time of each attempt, whether there was any specimen provided, the quantity of specimen provided (if possible), and the amount of fluids that the employee was given to drink.

Should the employee be monitored during the one-hour wait period?

The employee must remain at the collection site, in a monitored area designated by the collector, during the wait period. While there is no requirement for you to do so, **it is a good practice for you to inform the employee** that they are not permitted to leave the collection site and that doing so could lead an employer to determine that a refusal occurred.

What to do if the employee does not provide a sufficient specimen at the end of the wait period?

If the employee has not provided a sufficient specimen within one hour of the first unsuccessful attempt to provide the oral fluid specimen, you must:

- Discontinue the collection,
- Note on the "Remarks" line of the CCF (Step 2),

  - If the employee provided a "specimen that shows signs of tampering", note whether the specimen was discarded because the employee did not provide a second sufficient specimen.
- Immediately notify the DER.
- **You should also discard any specimen the employee provided** (to include any specimen that "shows signs of tampering") and
- Send Copy 2 of the CCF to the MRO and Copy 4 to the DER to notify the MRO and the employer of the problem.
  - You must send or fax these copies to the MRO and DER within 24 hours or the next business day. This is done even if the employee did not provide any specimen.

Should the collector sign the CCF when the employee does not provide a specimen?

Yes. You should:

- Check the box in Step 2 of the CCF (indicating that no specimen was provided) and provide an explanation in the "Remarks" section,
- Provide your name and signature in Step 4 of the CCF,
- Ensure the employee's name and telephone number are included on the MRO copy.
- Transmit the CCF copies to the appropriate parties (e.g., employer and MRO).

Why am I doing this? By signing the CCF, you are attesting to the fact(s) of the collection.

What happens if the employee refuses to provide a new specimen or leaves the collection site?

If the employee refuses to make the attempt to provide a new oral fluid specimen or leaves the collection site before the collection process is completed, you must:

- Discontinue the collection,
- Complete the CCF (including your printed and signed name in Step 4) and note the refusal event on the "Remarks" line of the CCF (Step 2), and
- Immediately notify the DER.
- **You should also discard any specimen the employee provided**.

This is reported to the DER as a "refusal to remain at the collection site" or a "refusal to provide an oral fluid specimen" [***see Section 10*** of these Guidelines].

Note: As with other collections situations, the collector is not required to inform the employee in a dry mouth situation that failure to remain at the collection site or otherwise failure to cooperate with the testing process constitutes a refusal. It is a **good practice for the collector to inform the employee** that such behavior could lead an employer to determine that a refusal occurred.

SECTION 10: REFUSAL TO TEST

Part 40 identifies those events that are considered a "refusal to test" [see § 40.191]:

- Some of these events are **based on an employer determination** (e.g., refusals that occur at a collection site)

  - Only the employer/DER can make this refusal determination.
- Some of the events are **based on an MRO determination** (e.g., the MRO determines there is no medical reason for a laboratory-reported adulterated or substituted result)
  - Only the MRO can make this refusal determination.

In all cases, it is your responsibility to fully document what occurred during the collection. What you document will help the employer or MRO with their decisions. Remember, ***do it right the first time and every time!***

When a refusal event occurs at a collection site, you must document what occurred during the collection and immediately notify the DER/Employer of the refusal event so the employer can make the refusal determination.

Why am I doing this? You are notifying the DER/employer that an event occurred that meets the refusal criteria. The employer is responsible for reviewing the evidence/documentation presented to make the refusal decision.

Below are the refusal to test events and the DOT regulatory instructions for handing them (see § 40.23, § 40.145, and § 40.191):

Event	Decision Maker	DOT Instructions
Fail to appear at a collection site when directed to report	**Employer / DER** [after review of the employer and collector documentation]	If the employee did not report to the site (except in the case of a pre-employment test) or did not arrive within a reasonable time, it is a refusal.
Fail to remain at the collection site	**Employer / DER** [after review of the collector documentation]	If the collector reports that the employee left the collection site before the testing process was complete, it is a refusal.
Fail to provide a specimen	**Employer / DER** [after review of the collector documentation]	If the collector reports that the employee left the collection site before providing a required specimen, it is a refusal. For pre-employment ONLY, it is not a refusal if the employee leaves the collection site or did not provide a specimen ***before*** the testing process commenced (i.e., the employee selects or was given the collection device by the collector).

Event	Decision Maker	DOT Instructions
Fail to provide a sufficient amount of specimen	**MRO**	If the MRO finds that there was no medical reason for the employee to provide an insufficient amount of specimen, it is a refusal.
Fail or decline to take an additional drug test the employer or collector has directed	**Employer / DER** [after review of the collector documentation]	If the employer or collector directs the employee to take an additional test, as required or permitted by the DOT, and the employee does not, it is a refusal.
Fail to undergo a medical examination or evaluation the MRO or employer has directed	**MRO**	If the employee does not go in for a medical evaluation or does not permit it to occur, it is a refusal. *Pre-employment only—it is not a refusal if there is no contingent offer of employment. In this case, the MRO will cancel the test.
Fail to cooperate with any part of the collection process	**Employer / DER** [after review of the collector documentation]	Some examples of failure to cooperate during an oral fluid collection are when the employee: 1. Refuses to empty pockets when directed; 2. Behaves in a confrontational manner that disrupts the collection process; 3. Fails to wash hands when directed; 4. Fails to remove objects from mouth; 5. Fails to permit inspection of the oral cavity; or 6. Fails to rinse when requested.
Adulterate or substitute a specimen	**MRO**	If the laboratory reports a confirmed adulterated or substituted specimen to the MRO and the MRO determines there is no medical reason for the result, it is a refusal.
Admit to the MRO to having adulterated or substituted the specimen	**MRO**	If the employee, during a medical review, admits to having tampered with their specimen, it is a refusal.

Is the collector required to inform the employee of what is a refusal event?

There is no requirement for you—the collector— to inform the employee that failing to remain at the collection site or otherwise failing to cooperate with the testing process constitutes a refusal. **It is a good practice to inform the employee** that such behavior could lead an employer to determine that a refusal occurred.

What does the collector do when there is a refusal event at the collection site?

As provided in § 40.191, immediately:

1) Stop the collection process,
2) Complete the CCF (including notes about the refusal event in the "Remarks" section (Step 2),
3) Notify the employer of the event, and
4) Transmit the completed CCF to the employer and MRO (as appropriate)

You should also:

Discard any specimen the employee provided.

Should the collector sign the CCF when the employee refuses a test?

Yes, as provided in § 40.191, you would provide your signature and the date and time in Step 4. You should also print your name on the form along with your signature. In addition, you should:

- In Step 2, check the box (indicating that no specimen was provided) and provide an explanation in the "Remarks" section,
- In Step 5 of the MRO Copy, ensure the employee's name and telephone number are included.

For a Pre-Employment test, when would you not report a refusal event?

In accordance with § 40.191, for a pre-employment test, you would **not report a refusal event** to the employer if:

- The employee fails to appear for the test; or
- The employee leaves the collection site or did not provide a specimen ***before*** the testing process commenced (i.e., the employee selects or was given the collection device by the collector).

Note: Although you do not report a refusal event to the employer, you will still need to immediately let the employer know that the collection event did not take place (see § 40.191(d)).

SECTION 11: UNUSUAL COLLECTIONS

Specimens with Abnormal Physical Characteristics

You must inspect each oral fluid specimen for unusual color, presence of foreign objects or material, or other signs of tampering.

Supporting evidence of an employee tampering could include, but is not limited to:

- an item in the employee's oral cavity that could have affected the collection;
- evidence of chewing on the collection pad or stick;

- foreign material in the tube that could have been introduced only by the employee; and
- an employee's admission to tampering with the specimen.

See ***Appendix D*** for examples of how an employee may attempt to tamper with an oral fluid collection.

SECTION 12: CORRECTING COLLECTION PROBLEMS

What is the collector's responsibility in correcting collection problems (§ 40.205)?

You have the responsibility of trying to complete a collection procedure for each employee successfully. If you become aware of a problem that can be corrected but has not already been corrected, you must take all practicable actions to correct the problem so that the test is not cancelled. 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.

Remember, ***doing it right the first time and every time*** will eliminate the need for corrective action.

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 initiate another collection as part of this effort.

You should not recall the employee for another collection once the employee has left the collection site.

What are the "Fatal Flaws"?

A fatal flaw is a discrepancy that cannot be corrected. If a fatal flaw exists, the laboratory will report "Rejected for Testing" to the MRO with an appropriate comment explaining why the specimen was not tested. Avoid a fatal flaw by ***doing it right the first time and every time!***

The fatal flaws in § 40.199 are:

(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 on the CCF;
(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);
(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;
(8) For an oral fluid collection, the collector used an expired device at the time of the collection; or
(9) For an oral fluid collection, the collector failed to enter the expiration date in Step 4 of the CCF and the laboratory is unable to determine the expiration date.

What must the collector do if a drug test is cancelled for which I was the collector?

If the laboratory reports a "rejected for testing" (because of a fatal flaw, or because you did not provide a memorandum/statement related to a correctable flaw), the MRO will cancel the test (see § 40.203(c)). If the reason for cancelling the test was due to your error, you must go through error correction training [***see Section 1*** of these Guidelines].

Will the laboratory ask the collector to correct an error or discrepancy?

Yes. In addition to checking for "fatal flaws," the laboratory will also check to see if the CCF has been properly completed by the collector.

If there is any discrepancy and/or error of omission on the CCF (i.e., you—the collector—did not sign the chain of custody, or the CCF failed to meet the requirements of § 40.40), the laboratory will contact you to determine if the discrepancy and/or missing information can be recovered. Recovery means you can provide a signed statement attesting to the fact that you inadvertently forgot to properly document the CCF (see § 40.205(b)).

Laboratories are required by HHS to retain these specimens for a minimum of 5 business days before they may be discarded; therefore, **it is critical that you respond on the same business day the laboratory requested the corrective action**. Remember—***do it right the first time and every time!***

Providing a statement or memorandum

Once the laboratory or the MRO contacts you, you should immediately provide a statement or memorandum to address the discrepancy and/or error of omission.

If the problem results 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 forgot to make a notation on the "Remarks" line of the CCF that the employee did not sign the certification. When the problem is brought to your attention, supply a signed statement that the employee failed or refused to sign the certification and that the collector's statement is true and accurate. You must supply this information on the same business day you are notified of the problem and transmit it by fax or courier.

If the problem is the use of a non-Federal CCF or an expired Federal form, you must provide a signed statement (e.g., a memorandum for record). The documentation must state that the incorrect form contains all the information needed for a valid DOT drug test and that the incorrect CCF was used inadvertently or as the only means of conducting a test in circumstances beyond the collector's control. The memorandum must also list the steps you—the collector—took to prevent future use of non-Federal or expired Federal CCFs for DOT tests. This information must be supplied to the laboratory on the same business day you are notified of the problem, and you must transmit it by fax or courier. Furthermore, for this flaw to have been corrected, the specimen must have been tested at an HHS-certified laboratory, where the test was conducted using the testing protocol in this part.

You must maintain a copy of the written and dated correction documentation with the appropriate CCF. You must also mark the CCF in such a way (e.g., stamp noting correction or

written notation) that it is obvious on the face of the CCF that the corrected (missing) information was supplied.

Can someone else sign a corrective statement on the collector's behalf?

If you make an error on a CCF and you are not available to sign a corrective statement (e.g., you are on vacation or no longer with the company), **your supervisor can sign** the corrective statement for you in certain circumstances, for example:

- If the error was the use of a non-DOT form (to include the use of the old Federal CCF), you or your supervisor may sign the corrective statement explaining the circumstances of why a non-DOT form was used or
- If the CCF contains the collector's printed name but no signature, you or your supervisor may attest that you performed the collection but did not sign your name.

Here are examples of when **your supervisor should not sign** a corrective statement on your behalf:

- If the employee's signature is omitted, and there is no notation in the "Remarks" line, only you can provide the corrective statement.
- If your missing information is the printed name and signature of the collector, neither you nor your supervisor may supply the missing information. This is a fatal, uncorrectable flaw.

SECTION 13: RECORD MAINTENANCE

You need to maintain your Collector copy (Copy 3) of the CCF for at least 30 days from the date of the collection unless otherwise specified by applicable DOT agency regulations (see § 40.79). All records should be maintained in limited access areas that permit no unauthorized entry.

In the case where the MRO copy (Copy 2) is faxed or the scanned image is securely sent to the MRO, you or the collection site should maintain the MRO copies together with the collector copy for 30 days. This is in the event the MRO requests another copy.

SECTION 14: QUESTIONS AND ANSWERS

1) Can an employer or training entities refuse to provide training records to a collector?

No. Collection sites and trainers who provide training for these service agents should not withhold training documentation from them when they have successfully completed the training requirements. If a collector is not in possession of training documentation, they are in violation of Part 40 (see § 40.35).

2) **If a collector makes a mistake resulting in a cancellation of a test before they have obtained qualification training, do they have to undergo error correction training?**

Yes, if a collector makes a mistake that causes a test to be cancelled, the collector must undergo error correction training (even if the collector has yet to undergo qualification

training). There are no exceptions to this requirement. Avoid error correction training by ***doing it right the first time and every time!*** (see § 40.35).

3) Who is responsible for notifying a collector that error correction training is needed?

The MRO, when canceling a drug test, will determine if the collector is at fault. When the MRO reports the cancelled test to the employer, the MRO will note the reason for the cancellation and that, if appropriate, it was the result of collector error. The employer or service agent (e.g., MRO or C/TPA) designated by the employer is responsible for notifying the collection site of the error (see § 40.35).

4) **Is error correction training required if a drug test is cancelled due to a specimen having an insufficient amount of oral fluid?**

If the laboratory finds there is an insufficient amount of oral fluid in the primary bottle for analysis, the laboratory will report to the MRO that the specimen is "rejected for testing" (unless the laboratory can re-designate the specimens). Subsequently, the MRO must cancel the test.

The MRO should seek to determine (with the assistance of the laboratory) if the specimen leaked in transit or if not enough oral fluid was collected. Specimen leakage while in transit to a laboratory will not cause a cancellation requiring the collector to have error correction training.

If the laboratory finds no evidence of leakage, indications would be strong that the collector failed to collect the appropriate amount of oral fluid. If this were the case, the collector would need error correction training.

If specimen leakage is a recurrent problem for a collection site, the MRO may want to inquire whether the shipping containers used are sufficient to adequately protect the specimens or whether collectors are securing the bottle lids properly.

5) What address is required for "Collection Site Address" in Step 1 of the CCF, and what telephone number should the collector provide?

The collection site address should reflect the location where the collection takes place. If the collection takes place at a clinic, the actual address of that clinic should be used, and not a corporate or a "main office" address of the clinic/collection company. (see § 40.40)

If the collection takes place on-site at the employer's place of business (e.g., a bus terminal, or a rail yard), the actual address of the employer site should be used.

If the collection takes place in a "mobile unit" or takes place at an accident site, the collector should enter the actual location address of the collection (or as near an approximation as possible, under the circumstances).

The required collector telephone number should be the number at which the laboratory, MRO, or employer, if necessary, may contact the collector and the collector's supervisor.

Pre-printing certain information onto the CCF is problematic if the information is subject to change.

6) Can a collector mark through pre-printed employer, MRO, collection site, and/or laboratory information on the CCF if that information is not accurate for a particular collection?

Yes. When the collector has no "blank" CCFs and the CCFs on hand contain inaccurate pre-printed employer, MRO, collection site, and/or laboratory information, the collector is permitted to "line through" the inaccurate information and insert the proper information legibly (see § 40.40).

The likelihood of a collection site having CCFs with inaccurate information increases with unexpected collection events (e.g., an employee arrives unannounced for post-accident testing).

If the specimen will be sent to a laboratory different than the one pre-printed on the available CCF, it becomes important for the collector to modify the CCF so that it reflects the name and address of the laboratory to which the specimen will actually be sent. It is also important for the collector to line through any preprinted billing code and insert the appropriate one if it is available.

Finally, laboratories should honor collection site requests to provide an adequate number of "blank" CCFs for use during unexpected collection events. It is important to note that the DOT permits overprinting or pre-printing of CCFs in an effort to streamline the entire testing process, not to limit the distribution of the forms to collection sites.

7) What if the employee does not arrive at the collection site at the employer's designated time?

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, the collector should contact the DER to determine the appropriate interval within which the DER has determined the employee is authorized to arrive. If the employee's arrival is delayed beyond that time, the collector should notify the DER that the employee has not reported for testing. (see § 40.61)

For a pre-employment test, it is <u>not</u> considered a refusal if the employee fails to appear for the test or if the employee leaves the collection site before being given a collection device by the collector (see § 40.191).

8) What if the employee admits to the collector that they adulterated or substituted the specimen, or behaves in a confrontational way that disrupts the collection process?

This is a refusal to cooperate with the testing process. The collector must terminate the collection process, immediately notify the DER of the circumstances surrounding the refusal event, and document them in the remarks section of the CCF (an additional memorandum

can also be prepared for the record, if appropriate) (§ 40.191). The collector should discard any specimen the employee previously provided.

9) Can the collector/collection site require the employee to sign a consent form or waiver when taking a DOT drug test?

No. As a service agent, 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 testing process. (§ 40.355) Collection sites (including medical clinics) should not use "generic" consent forms for DOT-required oral fluid specimen collections, even if their clinic policy requires consent from the general patient population.

10) Can a collector collect a specimen from more than one employee at a time?

To avoid distraction that could compromise security, a collector is limited to conducting a collection for only one employee at a time. However, during the 1-hour waiting period that an employee is consuming fluids (dry mouth), a collector may conduct a collection for another employee. In this case, the employee with the dry mouth must be properly monitored to ensure the continued integrity of the test (***see Section 9*** of these Guidelines). (§ 40.48)

11) What articles of clothing should an employee be told, or not told, to remove during a collection?

While the employee must be told to remove outer articles of clothing (e.g., coats or jackets), the employee must not be asked to remove other articles of clothing, such as shirt, pants, dress, or undergarments. Additionally, the employee **must not** be requested or required to remove all clothing to wear a hospital or examination gown. (§ 40.61)

An exception may be made if the employee is wearing a hospital gown as part of a physical examination authorized by a DOT operating administration's rule and a drug test is also being collected under Part 40.

Work boots or cowboy boots should not be removed unless the collector has a reason to suspect that the employee has something in the boots which may be used to adulterate or substitute a specimen.

When an employee is asked to remove his or her hat or head covering, and refuses to do so based on religious practice, it is advisable for the collector to exempt the employee from removal of the head covering unless the collector has an observable indicator that the employee is attempting to hide (inside the head covering) adulterants or other substances which may be used in an attempt to adulterate or substitute a specimen.

12) What is the collector to do if the seals don't adhere to the bottles or if the seals break when they are being applied to the bottles?

Occasionally, the tamper-evident label/seal provided with the CCF will not properly adhere to the specimen bottle because of environmental conditions (e.g., moisture,

temperature, or specimen bottle material) or may be damaged or broken during the collection process. When this occurs, the collector should use the following corrective procedures:

a. If the seal is broken **while being removed from the CCF form** or **during the application of the first seal on the primary bottle**, the collector should transfer the information to a new CCF and use the seals from the second form.

b. If one seal is already in place on a bottle and the **second seal is broken while being removed** from the CCF or is **broken during application on the second bottle** or while the **employee is initialing either seal**, the collector should:

- Initiate a new CCF and provide an appropriate comment on the "Remarks" line in Step 5.
- Place the seals from the second CCF perpendicular to the original seals to avoid obscuring the information on the original seals or the bottle's expiration date. As required by § 40.74, the seals must be initialed by the employee (both sets of employee initials should match).
- Draw a line through the Specimen ID number and bar code (if present) on the original seals to ensure the laboratory does not use that number for reporting the results.
- Not pour the specimen into new bottles.

c. In both cases, the collector should ensure that all copies of the original (first) chain of custody form are destroyed or disposed of properly (e.g., shredded, torn into pieces).

Because the specimen bottles are now sealed with tamper-evident tape and do not have to be under the employee's direct observation, the employee is allowed to wash his or her hands if the employee desires to do so.

> ***There is no corrective procedure available if the seal is broken after the employee leaves the collection site. The collector will still send the specimen (both bottles) to the laboratory pursuant to § 40.79 for the laboratory to process the specimen according to its procedures.***

13) What if the collector inadvertently reverses the bottle seals?

If the collector inadvertently reverses the seals (i.e., places the "A" bottle seal on the split bottle and vise-versa) and subsequently notices this, the collector should note this in the "Remarks" line, **leave the seals alone**, and continue the collection process. Laboratories have procedures that permit them to "re-designate" the bottles.

14) **How should a dry mouth collection be handled when the collectors change due to a shift change?**

Given the time span involved, it is possible that two collectors could be involved in a dry mouth collection (e.g., because of a shift change during the 1-hour period). In this situation, it is permissible for one collector to turn the process over to another collector to complete the collection.

The first collector should document the start time for the 1-hour period. According to § 40.79, the second collector would provide their name and signature after the second collection as the collector of record. The Remarks line (Step 2 of the CCF) should be used to document the transition (including the first collector's name and the start time for the dry mouth procedure).

15) Should the employee be told to come back the next day to complete the collection if the "dry mouth" wait period extends beyond the collection site's closing time?

If the collection site is closing and the employee has not completed the dry mouth process, the collector/collection site should make every effort to ensure the employee is afforded up to the one hour for a "dry mouth" situation. For example, the collector should contact the employer and make the necessary arrangements to complete the collection process. If the collection site is unable to afford the 1-hour period due to the collection site closing before it ends, the collection site should not conduct testing within that time period.

16) **What is the preferred method for the collector to get the MRO copy of the paper CCF to the MRO?**

The promptness of reporting suffers when the mail is used to convey the MRO copy from the collection site. Even though DOT permits other means (e.g., overnight courier service) of transmitting MRO copies from the collection site to the MRO, collectors should fax the MRO copies when possible (see § 40.79). If the faxed copy is not legible, the MRO should request another faxed copy or a hard copy.

[this space intentionally left blank]

APPENDIX A - Suggested Format: "Documenting Oral Fluid Collector Qualification Training Required by 49 CFR Section 40.35"

---This suggested format is not required to be used by 49 CFR Part 40---
---It is intended to provide a list of elements necessary to train an oral fluid collector---

On _____, the Collector, _____,
Print date Printed name & signature of the Collector trained

was trained in accordance with 49 CFR § 40.35, by: _____
Printed name & signature of the Trainer

to meet the qualification requirements of 49 CFR § 40.35.
The Basic Information Requirements:

- As a result of this training, I, the Collector, have initialed each of the following requirements that I am now knowledgeable about:
  - 49 CFR Part 40 (Part 40); _____
  - the "DOT Oral Fluid Specimen Collection Procedures Guidelines," _____
  - applicable DOT agency regulations for those DOT agencies for whom the collector will perform DOT-regulated collections; _____
  - other materials available from the Office of Drug and Alcohol Policy and Compliance (ODAPC). _____; and
  - I will keep current on any changes to the materials above. _____
  - In addition, as required, I have subscribed to the ODAPC list-serve at https://www.transportation.gov/odapc/get-odapc-email-updates

Qualification Training Requirements:

- I, the Trainer[1] have provided qualification instruction for this Collector on the following elements that I have initialed:
  - All steps necessary to complete a collection correctly _____;
  - All steps necessary to properly complete and transmit the CCF _____;
  - "Problem" collection scenarios (e.g., situations like "dry mouth" and attempts to tamper with a specimen) _____;
  - Fatal flaws, correctable flaws, and how to correct problems in collections_____;
  - The Collector's responsibility for:
    - maintaining the integrity of the collection process; _____
    - ensuring privacy; _____
    - ensuring specimen security; _____
    - avoiding conduct or statements that could be viewed as offensive or inappropriate. _____

[1] The person(s) conducting the training is qualified under 49 CFR § 40.35(c)(2).

Initial Proficiency Demonstration:

- After the completion of the qualification training noted above, the Trainer or a person qualified to do so[2], has monitored and evaluated, in person or by a means that provides real-time observation and interaction between the Trainer and the oral fluid Collector, the Collector's performance in completing five consecutive error-free mock collections. Both the Monitor[3] and the Collector will initial the following:
    - The 5 mock collections on _____ have included the following collection scenarios: Name of collection device
        - 1 uneventful collection; _____; _____ Monitor Collector
        - 1 insufficient quantity; _____; _____ Monitor Collector
        - 1 with something in the mouth that may interfere with the collection; _____; _____ Monitor Collector
        - 1 attempt to tamper with the specimen; _____; _____ Monitor Collector
        - 1 employee refusing to sign the CCF and initial the specimen bottles' tamper-evident seals; _____; _____ Monitor Collector

I served as the Monitor and I, attest that the five consecutive mock collections were all error-free.

_____ _____
Signature of the Monitor Date of Monitored Collections

_____
Signature of the Collector

_____
Signature of the Trainer

The collector should maintain a copy of this completed form as proof of training to provide this documentation on request to DOT, employers, and TPAs.

[2]The person(s) monitoring the error-free mock collections is qualified under 49 CFR § 40.35(c)(2).

[3] If someone other than the Trainer has monitored and evaluated the Collector's performance in real-time and confirmed the mock collections were error-free, then that Monitor's printed name, signature, and date of the mock collections have been added below.

APPENDIX B – COLLECTION SITE SECURITY AND INTEGRITY

DOT's Steps to Oral Fluid Collection Site Security and Integrity

Office of Drug and Alcohol Policy and Compliance
U.S. Department of Transportation

1. Maintain visual contact with the employee during the collection process.

2. Ensure that there is no unauthorized access into the collection areas.

3. Ensure access to collection materials and specimens is effectively restricted.

4. Ensure to maintain privacy to the employees and prevent distractions during the collection process. Post signs to indicate access is limited.

5. Perform only one collection at a time.

6. Make sure that employees show proper picture ID.

7. Make sure employees use hand sanitizer or wash their hands.

8. Keep employee's specimen within view of you and the employee between the time it was collected and sealed.

9. Maintain personal control of the specimen and CCF at all times during the collection.

APPENDIX C – DOT STANDARDS FOR ORAL FLUID COLLECTION DEVICES

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:

      i. 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.

      ii. 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.

   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 the device.

2. **Instructions**
   a. 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 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**

d. 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, or plastic container).

e. May be made available separately at collection sites rather than being part of an actual collection device sent to collection sites.

f. 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.

[this space intentionally left blank]

APPENDIX D – EXAMPLES OF TAMPERING WITH AN ORAL FLUID COLLECTION

- Attempting to rinse the mouth or gargle with mouthwash or other liquid (e.g., detox products, hydrogen peroxide, lemon juice, or vinegar) immediately before or during the collection
- Chewing gum, using dental products (e.g., dental floss), or holding items (e.g., lozenges, capsules) in their mouth before collection
- Attempting to hold a portion of collection-provided water in their mouth to dilute the specimen
- Attempting to cause bleeding (e.g., biting/chewing the cheek)
- Biting/Chewing the collection device
- Sucking the fluid out of the collection device, attempting to direct oral fluid away from collection pad, or swallowing excessively during collection process.
- Not positioning the collection device correctly in the mouth
- Attempting to conceal a foreign object (e.g., mint, breath strip, toothpaste, ice, liquid capsule, or cough drop) in the mouth
- Attempting to detach, rip, eat, swallow, or destroy the collection pad while in the mouth

[this space intentionally left blank]

APPENDIX E – OPERATING ADMINISTRATION RULES

49 CFR (§ 40.35(a)) states that collectors must be knowledgeable about the DOT agency regulations applicable to the employers for whom the collectors conduct oral fluid specimen collections. The following is a list of regulations which govern an employer's implementation of the DOT drug and alcohol testing rules:

The FMCSA regulation is 49 CFR Part 382.

The FRA regulation is 49 CFR Part 219.

The FAA regulation is 14 CFR Part 120.

The FTA regulation is 49 CFR Part 655.

The PHMSA regulation is 49 CFR Part 199.

The USCG regulation is 46 CFR Parts 4, 5, and 16.

Drug and alcohol testing (including collection) procedures are 49 CFR Part 40.

A short summary of the operating administrations' requirements can be found in our publication "***DOT Agency/USCG Drug and Alcohol Program Facts***". This publication and the actual regulations are available via our website http://www.transportation.gov/odapc.

[this space intentionally left blank]

APPENDIX F – Important reminders!

- **Ensure the oral fluid specimen you collected is sent to the correct laboratory listed on the CCF.**

- **Familiarize yourself with the employer's standing orders to know which collection method (oral fluid or urine) should be used in specific situations.**

- **Follow the manufacturer's instructions on whether or not you can re-use a device.**

- **Always verify that you are using a device that is not expired.**

- **If you choose not to provide oral fluid collection services as a collection site, you should let your current DOT-regulated employers know about your business decision.**

U.S. Department of Transportation
Office of the Secretary

Office of Drug and Alcohol Policy and Compliance

1200 New Jersey Avenue, S.E.
Washington, D.C. 20590

202.366.3784

202.366.3897 fax

http://www.transportation.gov/odapc

ODAPCwebmail@dot.gov