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

DOT Urine Specimen Collection Procedures Guidelines

Revised June 2026

About These Guidelines

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

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

These Guidelines are a complete revision of the previous version of all the DOT Urine Specimen Collection Procedures Guidelines, 49 CFR Part 40, for Transportation Workplace Drug Testing Programs. The current version replaces all previous versions, which are no longer valid guidance.

This document addresses and provides guidance concerning 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 the actual rule.

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.

This version of the DOT Urine Specimen Collection Procedures Guidelines contains minimal graphics and formatting to ease transmission and downloading of the document from the internet.

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.

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 employers to conduct drug testing in accordance with the 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 ensure the process is fair to employees.

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

It's important to understand that your actions during the specimen collection process are crucial, and ***you may be asked to testify*** about a specific collection that you performed. What you do during a collection matters!

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 ensure you understand the details and 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 collection process right. It explains how Part 40 addresses each step of the urine specimen collection process and how to handle issues that can arise during 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 to ensure 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 consistently. Other training materials include the drug testing rules of the DOT Operating Administrations (which tell you who will be tested and when), along with Part 40 Q&As that provide guidance on Part 40. All can be found on the ODAPC website http://www.transportation.gov/odapc.

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 collection. **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 Designated Employee Representative (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 conduct oral fluid testing, and some oral fluid testing laboratories will not conduct 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.

Note:

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

- 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.

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SECTION 1: THE URINE 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 provided, and initiates and completes the CCF.

Who can be a urine collector?

A person who has met all the requirements in 49 CFR Part 40 (§ 40.33) can be a urine collector, unless the person falls under the 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, 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 a urine 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:
  - May 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.
    - **For a monitored or observed collection**, the immediate supervisor may act as a monitor or observer (same sex) if there is *no one else available* at the collection site to conduct the monitored or observed collection.
- An **employee who is in a safety-sensitive position** and subject to the DOT drug testing rules
  - Should not be a collector, an observer, or a monitor for co-workers in the same testing pool or who work together with that employee daily. 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, and,
- The employee cannot be the collector of their own urine specimen.
- An **individual who is related to the employee (e.g., spouse, ex-spouse, or relative) or a close personal friend.**
  - Should not be a collector, as this requirement is to avoid a potential conflict of interest.

What are the training requirements under § 40.33?

To be permitted to act as a urine 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

You must

a) Be knowledgeable about and keep current on:
   i. 49 CFR Part 40,
   ii. "DOT Urine Specimen Collection Procedures Guidelines" and
   iii. DOT Agency regulations applicable to the employers for whom you perform collections,
b) 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) All steps necessary to complete a collection correctly and the proper completion and transmission of the Federal Drug Testing Custody and Control Form (CCF)
b) "Problem" collections (e.g., situations like "shy bladder" and attempts to tamper with a specimen);
c) Fatal flaws, correctable flaws, and how to correct problems in collections; and
d) 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 qualification training, you must demonstrate proficiency in collections by completing five consecutive error-free mock collections. Including:

- Two uneventful collection scenarios,
- One insufficient quantity of urine scenario,
- One temperature out of range scenario, and
- One scenario in which the employee refuses to sign the CCF and initial the specimen bottle tamper-evident seals.

Another person must monitor and evaluate your performance, in person or by a means that provides real-time observation and interaction between the instructor and trainee and attest in writing that the mock collections are "error-free."

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 urine collector who has demonstrated necessary knowledge, skills, and abilities by having:

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

The monitor in the 2nd and 3rd categories above does not need to practice actively as a urine collector if this person has met the collector qualification requirements.

NOTE: It is recommended that individuals arrange for both qualification training and initial proficiency demonstration training to be conducted simultaneously. The entire training process should be completed within 30 days of the start date. If the student has not completed the proficiency training within the 30-day timeframe, it is best practice for him/her to retake the qualification training component of the program.

(4) Error Correction Training

If you make a mistake in the collection process that causes a urine test to be cancelled (i.e., a fatal flaw (§ 40.199) or an uncorrectable correctable flaw (§ 40.203) [see page 43 of these guidelines for a list of fatal flaws], you must undergo error correction training:

a. This training must occur within 30 days of the date you are notified of the error that led to the need for error correction training.
    i. You may continue to perform DOT urine collections during this period. However, if you do not complete error-correction training within 30 days, you are no longer qualified to conduct DOT urine collections.
b. This training covers only the subject matter area(s) in which the error that caused the test to be cancelled occurs.
c. 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.
d. You must demonstrate your proficiency in the collection procedures of this part by completing three consecutive error-free mock collections:
    i. One uneventful scenario, and
    ii. Two scenarios related to the area(s) in which your error(s) occurred.
e. The person providing the training must monitor and evaluate your performance and attest in writing that the mock collections were “error-free.”

REMINDE: 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 on which 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 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 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/auditor/investigator can be confident that you fully meet 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 cannot demonstrate that you are qualified, you will need to complete the collector qualifications 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 application 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 a urine collector?
If you have additional questions regarding collector qualification training, please read our *How Can I Become a Urine Collector for DOT Drug Testing*? document on the ODAPC website: http://www.transportation.gov/odapc/collectors.

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 a urine 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 § 40.42.

The collection site must have:

1. A single-toilet room with a full-length privacy door or a multi-stall restroom. Whenever available, a single toilet restroom with a full-length privacy door is preferred. All types of restrooms, including a mobile facility (e.g., a vehicle with an enclosed toilet), are acceptable.
2. A source of water for washing hands that, if practical, is external to the restroom where urination occurs. If the only source of water available is inside the restroom, the employee may wash their hands, and then the collector must secure the water source (e.g., use tamper-evident tape or cut off the water supply) before the collection takes place. If water is not available at the collection site, the collector may provide moist towelettes outside the restroom.
3. 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.

Generally, there are two types of collection facilities:

1. A single-toilet restroom, with a full-length privacy door, or
2. A multi-stall restroom, with a partial-length door.

Using a multi-stall restroom:

If a single-toilet restroom is not available, a multi-stall restroom may be used. Such a site must provide substantial visual privacy (e.g., a toilet stall with a partial-length door) and meet all other requirements regarding sources for washing hands and a work area for completing paperwork. Additionally, as the collector, you must either:

1. Secure all sources of water and other substances that could be used for adulteration and substitution (e.g., water faucets, soap dispensers) and place bluing agent in all toilets and/or secure the toilets to prevent access; or
2. Conduct all collections as monitored collections. ***See Section 11***.

Except for the monitor in the event of a monitored collection or the observer in the event of a directly observed collection, only the employee may be present in the multi-stall restroom during the collection.

Where is the collector's work area?

The collector's work area may be located outside the restroom. However, if there is no appropriate space available outside the restroom to serve as a secure, clean work area and the restroom is either a multi-stall facility or a single-stall facility with a partial door for privacy and is large enough to accommodate a work area, the collector may locate the work area inside the restroom as long as all procedures for a monitored collection are met.

SECTION 3: SECURING A COLLECTION SITE

How does the collector secure the 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 requirements of § 40.43, 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 must also ensure that no soap, disinfectants, cleaning agents, or other possible adulterants are present, and water sources are unavailable to the employee
3. Procedures to ensure that all authorized persons are under the supervision of a collector at all times when permitted into the site; and
4. Procedures to provide for the secure handling and storage of specimens.

If the collection site uses a facility normally used for other purposes, such as a public restroom or hospital examining room, you must also ensure that:

1. Access to collection materials and specimens is effectively restricted; and
2. The facility is secured against access during the procedure to ensure privacy to the employee and prevent you from being distraction.
    a. Limited-access signs must be posted.

See "DOT's 10 Steps to 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 the observer (in a direct observation collection) and the monitor (in a monitored collection) are allowed in the area where the employee provides a 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:

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

3. If a movable toilet tank top cannot be secured shut, a bluing (coloring) agent needs to be added to the toilet bowl/water tank to deter/prevent an employee from diluting the specimen.

Recommended for use:

1. Single-use disposable gloves for use by collectors while handling specimens,
2. Tamper-evident tape for securing water sources (e.g., faucets, toilet tank tops, and other appropriate areas),
3. Signs, when necessary, can be posted to prevent entry into collection areas.

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

Ensure that you have enough and the correct **supplies** to conduct a collection. Be sure to check your supplies **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 kit is required for each employee (e.g., an immediate recollection under direct observation). When using the 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 an oral fluid specimen collection (using a new CCF) to complete the collection.
>
> If you are also a qualified oral fluid collector, you should always bring some oral fluid devices to the collection in the event you need to switch to an oral fluid specimen collection.

SECTION 5: FEDERAL DRUG TESTING CUSTODY AND CONTROL FORM

When is a CCF Used?

The CCF must be used to document every urine 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 of 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

You can find the CCF on DOT's website (http://www.transportation.gov/odapc/collectors) 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 several 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 the 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 the 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/workplace.

Is the collection process any different when the collector uses the 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).

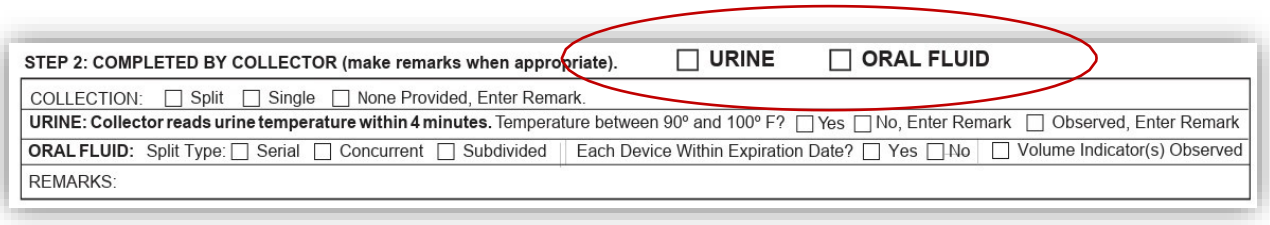
For a combination of electronic and paper CCF that has been signed electronically by the collector and employee, the laboratory requires the collector to send the "authoritative copy" (i.e., printout of Copy 1 of the electronic CCF) with the specimen. If there is a problem with printing the authoritative 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 the electronic CCF, you must establish adequate confidentiality and security measures to ensure that confidential employee records are not available to unauthorized people. 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 will 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 90º and 100º 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:

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 a urine 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, phone 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, phone 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. Whether the test is to be observed or not (see § 40.67(a) & (b)).
10. (Optional) C/TPA name, address, phone, 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 an oral fluid 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 Am I Doing 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 has already shown it at the front desk 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.
2. Any other identification allowed under a DOT operating administration's rule.

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, 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 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: URINE 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**. To do so, you must do the following before each collection (see § 40.43):

1. Secure any water sources or otherwise make them unavailable to employees (e.g., turn off water inlet, tape handles to prevent opening faucets);
2. Ensure that the water in the toilet and tank (if applicable) has bluing (coloring) agent in it. Tape or otherwise secure shut any movable toilet tank lid, or put bluing in the tank;
3. Ensure that no soap, disinfectants, cleaning agents, or other possible adulterants are present;
4. Inspect the site to ensure that no foreign or unauthorized substances are present;

5. Ensure that undetected access (e.g., through a door or window not in your view) is not possible.
6. Secure areas and items (e.g., ledges, trash receptacles, paper towel holders, under-sink areas, dropped ceilings) that appear suitable for concealing contaminants and
7. Recheck items (1) through (6) following each collection to ensure the site's continued integrity.

NOTE: See "DOT's 10 Steps to Collection Site Security and Integrity" in ***Appendix B***.

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 restroom, use anything located in the restroom, or have something given to them while in the restroom. 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 they are unable to urinate (see § 40.61). If an employee tells you, upon arrival at the collection site, that they cannot provide a specimen, you must still begin the collection procedure regardless of the reason given. 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].

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/workplace) and DOT (https ://www.transportation.gov/odapc) websites (see § 40.61).

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.

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, fax number, and I.D. number*** (if applicable)
  - An employer must provide you with 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 Commercial Driver's License (CDL), or any other State-issued or Federally-issued identification number.
    - Drivers tested under the authority of the FMCSA need to provide their 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 to be checked when it is a USCG Periodic test.

- **Step 1F:** ***Other Tests to be Performed (specify)***
  - You do not need to complete this step (leave this space blank). The laboratory will know what drug testing panel to run based on the account number on the CCF.

- **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 17:*** Question #5].

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 in the bathroom) 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, you may place the medication in a locked cabinet, if available. Alternately, 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 their 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, 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 12*** 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 to do with items an employee brings to the collection site?

If you observe materials brought to the collection site (e.g., suspected urine, plastic bags with fluid in them, artificial or mechanical objects for providing substituted urine, etc.), or the employee's conduct clearly indicates an attempt to adulterate, substitute, or alter the specimen, you must make note of the conduct on the CCF and conduct a directly observed urine collection [***See Section 10*** of these Guidelines] or an oral fluid collection.

> Remember, if the employer requires it, the direct observation collection may be an oral fluid specimen collection.
>
> Make sure you are familiar with the employer's "standing orders" regarding oral fluid specimen collections.

If the item that could be used to adulterate/substitute the specimen (e.g., eye drops) appears to have been brought inadvertently to the collection site, secure it, and proceed with the collection. For example, a bottle of eye drops may have been brought inadvertently and have to be secured by the collector, and the collection would proceed. 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).

Items that were found, such as suspected urine, plastic bags with fluid in them, artificial or mechanical objects for providing substituted urine, etc., 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.

Is the employee required to wash his and 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.

The employee may use soap, and if practicable, it should be a liquid or cream. A solid bar of soap gives the employee the chance to conceal soap shavings under his or her fingernails and use them to attempt to adulterate 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 12*** of these Guidelines].

How does the employee receive a collection container?

Who selects the collection container is up to you. Either you can select the collection kit or collection container (if it is separate from the kit) 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 kit or collection container. (As best practice, you should do this since you may break the seals more efficiently.)

The collection container must be sealed or individually wrapped in a sealed plastic bag or shrink wrapping or must have a peelable, sealed lid or other easily visible tamper-evident system. **Do not unwrap or break the seal on any specimen bottles at this time**. Unwrap only the collection container.

Ensure the employee takes only the collection container into the room used for urination. The sealed specimen bottles remain with you.

What procedures are used for the employee to provide their urine specimen?

Direct the employee to:

- go into the secured room used for urination,
- provide a specimen of at least 45 mL,
- not to flush the toilet, and
- return with the specimen as soon as possible after completing the void.

You may **set a reasonable time limit** for the employee to be inside the bathroom, and this time frame should be explained to the employee.

You should also tell the employee that the temperature of the specimen is a critical factor, and that the employee should bring the specimen to the collector as soon as possible after urination. You should inform the employee that if it is longer than 4 minutes from the time the employee urinates into the container and you read the specimen temperature, the potential exists that the specimen may be out of range, and an observed collection may be required.

If the employee tells you, at the beginning of the collection process, that they cannot provide a specimen (e.g., because they just went to the bathroom, etc.), you must still begin the collection procedure regardless of the reason.

What if the employee inadvertently flushes the toilet?

In many restrooms, a toilet tank into which the bluing agent may be placed is inaccessible. When the employee flushes the toilet, they can potentially use the clear (un-blued) water to dilute the specimen.

If you determine the employee inadvertently flushed the toilet, no corrective action or recollection is necessary. However, to guard against this action, you may want to place a sign with instructions not to flush by the toilet handle or secure the handle with tamper-evident tape. For "auto flush" devices, you may want to cover the sensor in some manner so that it does not activate when the employee is providing a specimen.

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

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 bottle caps/lids. If practical, you may permit the employee to wash their hands right after the employee gives you the collection container (and you checked the temperature), provided you and the employee can still maintain visual control of the specimen collection container.

After the employee gives you the specimen container, you must (see § 40.65):

(1) Check the amount of urine provided,
(2) Check the temperature of the specimen, and
(3) Inspect the specimen for adulteration or substitution.

(1) ***Check the amount of urine provided***.

Make sure the specimen contains a sufficient amount of urine (a minimum of at least 45 mL).

a. ***If the volume is 45 mL or more***, proceed with the collection procedures described in § 40.71.

b. ***If there is less than 45mL*** and the specimen ***temperature is in the acceptable*** range:

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 "shy bladder process" [***see Section 9*** of these Guidelines].

c. ***If there is less than 45 mL*** and the ***specimen temperature is NOT in the acceptable*** range:

i. Do not discard the specimen,
ii. Complete the collection process for the "out of temperature range" specimen; and
iii. **Immediately begin** a second collection under direct observation [***see Section 10*** of these Guidelines].

> Remember, if the employer requires it, the direct observation collection may be an oral fluid specimen collection.
>
> Make sure you are familiar with the employer's "standing orders" regarding oral fluid specimen collections.

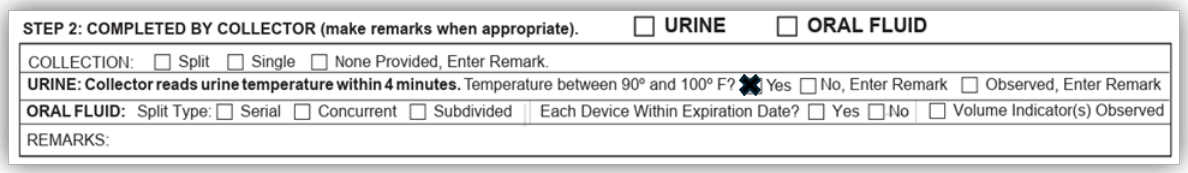
(2) ***Check the temperature of the specimen.***

a) You must **check the temperature** of the specimen no later than four minutes after the employee has given you the specimen.

b) The acceptable temperature range is 32-38 °C/90- 100°F.

c) You must determine the temperature of the specimen by reading the temperature strip attached to the collection container [see ***Appendix C*** of these Guidelines for requirements of a collection kit].

d) If ***the temperature is within the acceptable range***, check the "Yes" box in Step 2 on the CCF and proceed with the collection procedure.


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

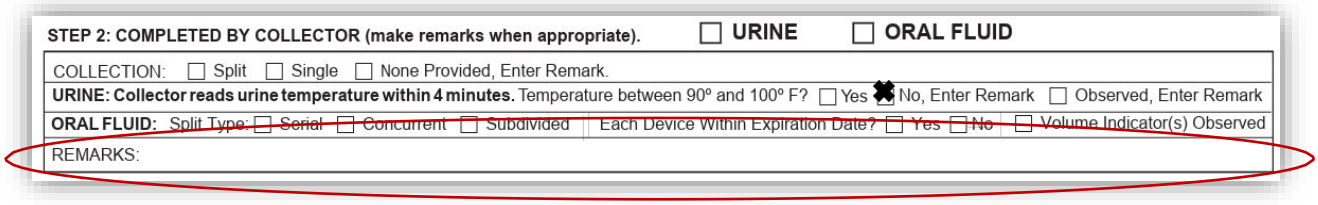
ORAL FLUID: Split Type: ☐ Serial ☐ Concurrent ☐ Subdivided | Each Device Within Expiration Date? ☐ Yes ☐ No ☐ Volume Indicator(s) Observed

REMARKS:

e) ***If the temperature is outside the acceptable range***, check the "No" box and enter in the Remarks line your findings about the temperature in Step 2 of the CCF. Complete the collection procedures for this specimen and **immediately begin** a second collection using direct observation procedures [***see Section 10*** of these Guidelines].

i. Use a second CCF and a new urine collection kit for the direct observation collection ["second" specimen].
ii. You must, as soon as possible, inform the collection site supervisor and the DER that a collection took place under direct observation and the reason for doing so.

(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".)


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:

Note: By documenting in the remarks section, you are ensuring the laboratory and MRO will know that two separate specimens are being submitted, the first one possibly being adulterated or substituted.

There is no requirement to take the employee's body temperature if the specimen temperature is out of range. If you suspect that the temperature strip was not activated, you should pour the urine specimen into another collection container with a temperature strip or into a specimen bottle that has a temperature strip attached and use this method to determine the specimen temperature. Do not introduce any other object (e.g., litmus paper, testing strips, etc.) into the specimen in the collection container or the bottles.

(3) Inspect the specimen for signs of tampering or adulteration.

a. Check for unusual color, presence of foreign objects or material, or other signs of tampering or adulteration. (see § 40.65)

b. If it is apparent from this inspection that the employee has adulterated or substituted the specimen (e.g., the specimen is blue, exhibits excessive foaming when shaken, smells of bleach), you must:

i. Complete the collection process for the suspect specimen and, as a best practice, document the unusual characteristics in the Remarks section of the CCF
ii. **Do not discard the suspect specimen**, but instead prepare the suspect specimen for shipment to the laboratory and
iii. **Immediately begin another collection under direct observation** [***see Section 10*** of these Guidelines].

c. If the employee provides a second urine specimen, both the "first" [suspect specimen] and "second" [direct observation] specimens are sent to the laboratory for testing. This is true even when the original specimen has insufficient volume but shows signs of tampering.

(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").

> Remember, if the employer requires it, the direct observation collection may be an oral fluid specimen collection.
>
> Make sure you are familiar with the employer's 'standing orders' regarding oral fluid specimen collections.

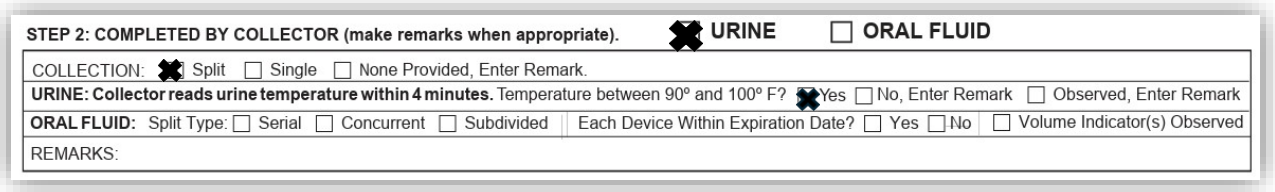
In either scenario (temp out of range or signs of tampering or adulteration), if the employee refuses to provide a "second" specimen:

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
5. **Discard any specimen** the employee previously provided.
6. The employer must decide whether the employee's actions constitute a refusal. [***See Section 12*** 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. After the employee hands you the collection container and **you have checked the specimen for volume, temperature, and signs of tampering**, you unwrap or open the specimen bottles. (You may permit the employee to do this; however, the recommended "best practice" is for you to perform this procedure.) Bottles may be shrink-wrapped or secured by other easily discernible tamper-evident methodology and may be wrapped separately or together.

After the collection, check the box on the CCF in Step 2 indicating that this was a "Urine" and "Split" specimen collection.


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 90º and 100º 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:

You, not the employee, must pour at least 30 mL of urine from the collection container into one specimen bottle, then place and secure the lid/cap on the bottle. This will be the primary specimen or "A" bottle.

You, not the employee, must pour at least 15 mL into the second bottle, then place and secure the lid/cap on the bottle. This will be the "B" bottle used for the split specimen.

> **Note**: You may first pour the requisite amount of specimen into each bottle and then secure the lids/caps on each bottle.

Try not to fill the primary or split specimen bottle up to the lid/cap because a completely full bottle is more likely to leak in transit. Additionally, when a split specimen bottle is full and subsequently frozen, it may cause the bottle to crack and leak during transit as the specimen thaws.

You, not the employee, must then remove the tamper-evident seals from the CCF and place them on each bottle. You should also ensure that the seal labeled as "A" is placed on the primary bottle with at least 30 mL of urine and that the seal labeled as "B" is placed on the bottle with at least 15 mL of urine. The seal must be placed over the lid/cap and down the sides of the bottle to ensure that the lid/cap cannot be removed without destroying the seal. ***The employee must be present to observe the sealing of the specimen bottles.*** (see § 40.71)

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 § 40.71)

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 17***, 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 telephone number, email address, and date of birth.

If the employee refuses to sign the form or provide a 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

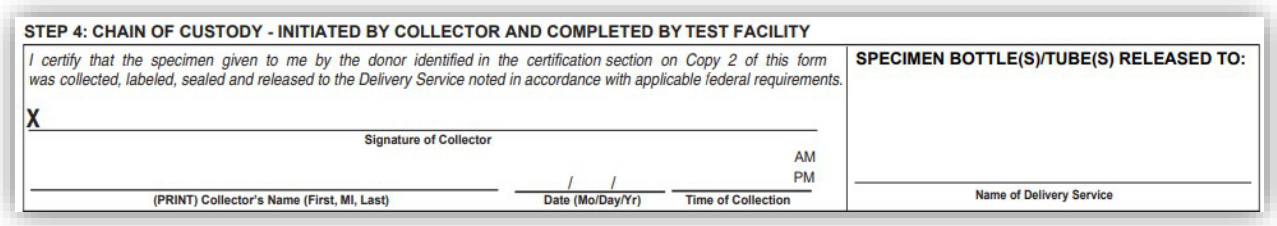
out any information, you must, as a minimum, print the employee's name in the appropriate place.

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

How does the collector package the specimen?

As requested 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 the temperature 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. You should ensure that the employee's copy includes the same information as the electronic CCF. You should provide the paper copy of Copy 5 to the employee while the employee is still with you.

You may now advise the 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 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 scanned and the image sent to the MRO's secure computer, it may be faxed to the MRO's secure fax machine, or it may be mailed or sent by courier to the MRO

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 copy 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 are 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.

Why is the collector role so important? What you do matters and can significantly impact the outcome of the testing event. For example, if your actions lead to a test being canceled, it results in additional costs for the employer. Additionally, you will be required to complete error correction training. ***Do it right the first time and every time!***

SECTION 9: INSUFFICIENT QUANTITY OF URINE

This is a situation in which the employee does not provide a sufficient amount of urine (45 mL) (see § 40.193).

The employee demonstrates their inability to provide a sufficient specimen when they come out of the restroom with an insufficient quantity of specimen or an empty collection container.

The employee's first insufficient specimen
If the employee provides an **initial insufficient specimen**, you discard the insufficient specimen. You then annotate in the "Remarks" line the time when the employee provided the insufficient specimen. After their first insufficient specimen, the employee is afforded a wait period to provide a sufficient specimen. You would use the same CCF to document subsequent urine collections.

Note: If there was no specimen provided on an attempt, the same collection container may be used for the next attempt (the employee may keep possession of the container during the waiting period).

Remember, if the employer requires it, you may need to switch to an oral fluid specimen collection during an "insufficient urine specimen" collection. If no one is qualified to conduct the alternate collection, contact the employer so the employer can make arrangements at another collection site. Make sure you know what employer wants to have done in this scenario.

If the employer requires an oral fluid specimen collection and you are qualified to collect an oral fluid specimen, discard the CCF for the insufficient urine specimen and begin a new CCF for the next specimen collection with a notation in the remarks section of the new CCF.

When does the wait period begin?

The wait period begins when the employee demonstrates their inability to provide a valid specimen after their first attempt (i.e., when the employee comes out of the restroom with an insufficient quantity of specimen or an empty collection container). It is important for you to ensure the employee goes into the restroom to try to provide a specimen for the wait period to begin.

How long is the wait period?

The employee is to be afforded **a wait period of up to three (3) hours** from when they provided their first insufficient specimen. The collector/collection site is to make every effort to ensure the employee is provided the full wait period [***see Section 17***: Question # 16 of these Guidelines].

The wait period should not extend beyond 3 hours. For example:

An employee presents an insufficient amount of urine at noon (12 o'clock) and is urged by the collector to drink up to 40 ounces of fluid distributed through a period of up to 3 hours (3 o'clock, in this example).

-- At 2 o'clock, the employee indicates that they can now provide the specimen, enters the collection area, but returns with a specimen outside the acceptable temperature range.

-- The collector immediately conducts an observed collection, but the employee – for the second time during this collection event, which began at noon – provides less than 45 mL of urine.

-- The employee has up to 3 o'clock and any remaining fluids to provide an adequate amount of urine under direct observation: The employee is not given an additional three hours and is not offered an additional 40 ounces of fluids.

What happens during the 3-hour wait period?

You explain to the employee the process for a shy bladder collection and urge the employee to drink up to 40 ounces of fluids, distributed reasonably through a period of up to three hours or until the individual has provided a sufficient urine specimen, whichever occurs first.

- It is <u>not a refusal</u> to test if the employee <u>declines</u> 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 require a medical evaluation.

Note: It is best business practice, but 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., 40 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 every half hour may not produce a sufficient specimen, although, in total, the amount would have been at least 45 mL. In this case, you need to determine if a longer time is needed for the employee to consume fluids and produce a sufficient volume of specimen. A good practice would be to ask and not require the employee to make another attempt during the three-hour wait period. However, within the three-hour wait period, the employee would be required to make an attempt.

Under no circumstances can you "combine" urine collected from separate voids to create one specimen of sufficient volume.

You should maintain a record in the "Remarks" line on the CCF of the time of each attempt, whether any specimen was 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 three-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 to do so, it is good practice to inform the employee that they are not permitted to leave the collection site and that doing so could lead the 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 three hours of the first unsuccessful attempt to provide the urine specimen, you must:

- Discontinue the collection,
- Note the fact on the "Remarks" line of the CCF (Step 2),
- If the employee provided an "out of temperature range specimen" or "specimen that shows signs of tampering," note that it was discarded because the employee did not provide a second sufficient specimen.
- Immediately notify the DER.
- **Discard any specimen the employee provided** (to include any specimen that is "out of temperature range" or "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 urine 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 a urine specimen" [***see Section 12*** of these Guidelines].

Note: As with other collection situations, the collector is not required to inform the employee in a shy bladder situation that failure to remain at the collection site or otherwise failing 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: DIRECTLY OBSERVED URINE COLLECTIONS

A directly observed urine collection procedure is the same as a routine urine collection procedure, with the additional requirement that an observer directly watches the urine go from the employee's body into the collection container [***See Appendix D*** of these Guidelines].

An oral fluid collection is considered a direct observation collection for purposes of Part 40.

When Part 40 calls for a "direct observation" collection, make sure you know what type of specimen collection the employer wants to have collected (urine or oral fluid).

If you are also a qualified oral fluid collector and are switching from a urine specimen collection to oral fluid specimen collection:

- Complete the urine specimen collection (including the CCF if you are sending the urine specimen to the lab), then
- Begin the oral fluid specimen collection **using a new CCF** and
- In the ''Remarks'' section of the new CCF, document the reason for the changed collection process so the MRO knows to expect two results (one from the urine collection and one from the oral fluid collection).

What are the reasons for conducting a direct observation collection (see § 40.67)?

The employer or DER directs you - the collector (or collection site) - to conduct a collection under direct observation when:

1. The laboratory reports an invalid specimen, and the MRO reports that there was not an adequate medical explanation for the result.
2. Because the split specimen test could not be performed (e.g., split lost, inadequate volume).
3. The MRO reports a negative-dilute result with a creatinine concentration greater than or equal to 2 mg/dL but less than or equal to 5 mg/dL; or
4. The test is a return-to-duty or follow-up test.
    a. The employer is required to conduct a directly observed collection with no advance notice to the employee.

As the collector, you must immediately conduct a direct observation collection when:

1. Directed to do so by the employer or DER (see paragraph above).
2. You observed materials brought to the collection site or the employee's conduct clearly indicated an attempt to tamper with a specimen; or
3. The temperature on the original specimen was out of range or the specimen appeared to have been tampered with.

As a collector, if you learn that a directly observed collection should have taken place but was not, you must inform the employer that the employee must be directed to return for an immediate recollection under direct observation.

An employee cannot "volunteer" to have their specimen collected under direct observation.

What does it mean to immediately conduct a direct observation collection?

Immediately means to begin the direct observation collection without delay. For example, when the employee provides a specimen out of temperature range, you should not wait to begin the direct observation collection because the employee says they cannot provide a specimen at this time. You would complete the first collection (seal the out of temperature specimens and complete the paperwork) and immediately begin the direct observation collection.

As a collector, you should always be prepared to conduct direct observation collections. As a collection site, an observer should be available at all times. If your site does not have the capability to perform direct observation collections, it is a good business practice to let all the DOT-regulated employers [for which you provide DOT-regulated services] know this ahead of time so they can make the necessary arrangements to have a direct observation collection performed when needed.

Who can be the observer?

The observer must be the same sex as the employee; there are no exceptions to this requirement.

You may serve as the observer when you are the same sex as the employee. If not, you must call upon another individual (who is the same sex as the employee) to act as the observer.

If a same sex observer cannot be found and oral fluid drug testing is not available, you must contact the DER for the same-sex observer to be present and conduct the directly observed urine collection.

If a same sex observer cannot be found and oral fluid testing is available, the collector must follow the employer's standing orders. If the standing order allows for an oral fluid collection, the collector will follow it. If no one is qualified to conduct the oral fluid collection, contact the employer so the employer can make arrangements at another collection site for the oral fluid test.

If the employer does not have a standing order, the collector must contact the DER, who will direct the collector to either conduct an oral fluid collection if the collection site can or send the employee to a collection site acceptable to the employer for the oral fluid test. The collector should document the attempt(s) made to contact the DER and proceed with an oral fluid collection if contact cannot be made.
another collection site for the oral fluid test.

What are the instructions to the observer?

If you are not the observer, you must verbally instruct the observer as to the procedures the observer must follow. Specifically, inform the observer not to take the specimen from the employee but to have the employee bring it to you, the collector. It is recommended that the collector have a short-written outline of the direct observation procedures to provide to and review with the observer. One version that could be used is provided on ODAPC's website: https://www.transportation.gov/odapc/DOT_Direct_Observation_Procedures.

What are the direct observation procedures?

1. You must explain to the employee why a directly observed collection is being conducted. If the directly observed collection is requested by the employer, you may state the reason (if known) or may only state that the employer requested a directly observed collection.

2. Unless you started the collection as a directly observed collection (e.g., return-to-duty or follow-up test), you must complete a new CCF for the directly observed collection.

    a. In Step 1(E), check the same "reason for test" box as for the first collection unless it is a return-to-duty or follow-up test,
        i. For example, if the first collection was "random," the direct observation collection will also be checked as "random."
    b. In Step 2, check the "Observed, (Enter Remark)" box, enter the reason in the "Remarks" line, and the name of the observer if it is someone other than the collector.
    c. **In a case where two sets of specimens are being sent to the laboratory** (e.g., because of suspected tampering with the first specimen), in Step 2 on each specimen's CCF, enter in the "Remarks" line a notation to this effect (e.g., collection 1 of 2, or 2 of 2) and the CCF specimen ID number of the other specimen.

3. The same sex observer enters the restroom or facility where urination occurs with the employee. The observer must request the employee to raise their shirt, blouse, or dress/skirt, as appropriate, above the waist, and lower clothing and underpants to show the observer, by

turning around, that the employee does not have a prosthetic device. After the observer has determined that the employee does not have such a device, the observer may permit the employee to return their clothing to its proper position and then conduct the observed collection.

Note: There are three basic types of prosthetic devices employees could "wear." [Of course, there could be other devices; here are examples of some devices]:

a. One device has a long plastic tube connected to a bottle containing heated urine.
b. Another device consists of a short plastic tube attached to a battery-heated plastic bag.
c. One device goes a step further by replacing the tube with very realistic prosthetic genitalia designed to match the employee's skin tone.

4. The observer must watch the employee urinate into the collection container. Specifically, the observer must directly watch the urine go from the employee's body into the collection container (mirrors or video cameras are not permitted). Standing behind the employee does not count as a directly observed collection.

   Note: If it is a multi-stall restroom, the observer must enter the stall with the employee.

   With respect to directly observed collections, the following situations are considered refusals to test [***see Section 12*** in these Guidelines]:

   a. The employee declines to allow a directly observed collection required or permitted by Part 40 to occur.
   b. The employee fails to follow the observer's instructions to raise and lower their clothing and to turn around to permit the observer to determine if the employee has a prosthetic or other device that could be used to interfere with the collection process.
   c. The employee possesses or wears a prosthetic or other device that could be used to interfere with the collection process.

   Note: In any of these situations, you discard any specimen the employee provided previously and notify the DER of the refusal event so the employer can make the refusal determination [***See Section 12*** of these Guidelines].

5. After the employee has completed urinating into the collection container, the employee and observer leave the enclosed toilet stall/restroom, and the employee hands the collection container directly to you, the collector. The observer must maintain visual contact with the collection container until the employee hands the container to the collector. If the observer is the collector, the collector may receive the collection container from the employee while they are both in the enclosed toilet stall/restroom.

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SECTION 11: MONITORED COLLECTIONS

A monitored collection is one that is conducted under less than completely private conditions, utilizing a multi-stall restroom.

What are the reasons for conducting a monitored collection?
If there is no practicable workplace outside of the restroom, the collector may set up an area within the multi-stall restroom to be used as a work area and for finalizing the required paperwork. (A collection that is not monitored may also be conducted in a multi-stall restroom, provided that the collector secures all of the stalls (bluing agent, etc.), secures all water sources and other potential sources of adulterants (soap dispensers) in the restroom, and posts signs or otherwise secures the restroom from entry by unauthorized personnel.)

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

What are the procedures for a monitored collection (see § 40.69)?
1. You must secure the room being used for the monitored collection so that no one except the employee and the monitor can enter it until after the collection has been completed.

2. If someone other than you is to monitor the collection procedure (e.g., the collector is not a medical professional), you must verbally instruct that person to use the following procedures (if the collector is the monitor, the collector must also follow these procedures):
    a. A monitor stands outside the stall and **does not watch the employee urinate.** If the monitor hears sounds or makes other observations indicating an attempt by the employee to tamper with a specimen, an additional collection must be conducted under direct observation.
    b. A monitor must ensure that the employee takes the collection container directly to the collector as soon as the employee has exited the enclosure.

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

4. If the employee declines to permit a collection authorized under Part 40 to be monitored, it is a refusal to cooperate in the testing process [***See Section 12*** in these Guidelines].

SECTION 12: 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** (i.e., no medical reason for the employee to provide an insufficient amount of urine; 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 handling 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 does not provide a specimen ***before*** the testing process commences (i.e., the employee selects or was given the collection device by the collector).
Fail to permit a monitored or observed urine collection	**Employer / DER** [after review of the collector documentation]	If the employer ordered an observed collection or if the collector required the collection to be monitored or observed, it is a refusal if the employee does not permit it to occur.

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 a urine collection are when the employee: 1. Refuses to empty pockets when directed; 2. Fails to wash hands when directed; 3. Admits to having adulterated or substituted the specimen; or 4. Has a device, such as a prosthetic appliance, to interfere with providing an actual urine specimen.
For an observed urine collection, fail to follow the instructions to raise and lower clothing and turn around	**Employer / DER** [after review of the collector documentation]	If the employee does not follow these instructions so that the observer can check for a prosthetic or other devices that could be used to interfere with the collection process, it is a refusal.
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.

Event	Decision Maker	DOT Instructions
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 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,
4. **Discard any specimen the employee provided**, and
5. Transmit the completed CCF to the employer and MRO (as appropriate)

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

Yes, as provided in § 40.191, you would provide your name and signature, and the date and time in Step 4. In addition, you should:

- In Step 2, check the box (indicating that no specimen was provided) and provide an explanation in the "Remark" 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 kit or cup 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 13: UNUSUAL COLLECTIONS

Medical Treatment and Catheterization

If an employee needs medical attention (e.g., an injured employee in an emergency medical facility who is required to have a post-accident test), do not delay this treatment to collect a specimen.

A urine specimen must not be collected, by catheterization or other means, from an unconscious employee to conduct a DOT-required drug test.

Catheterization of a conscious employee to obtain a urine specimen for a DOT-required test (i.e., specifically to obtain the specimen, as distinct from catheterization resulting from medical treatment) is also not authorized.

However, an employee who normally voids through intermittent or self-catheterization is required to provide a specimen in that manner if they are required to produce a specimen for a DOT test. If able to, the employee may provide the specimen directly from the catheter into the collection container in the privacy of a restroom. If an employee who normally voids through self-catheterization declines to do so, this would constitute a refusal to test (see § 40.61).

If an employee is catheterized as part of a medical procedure (e.g., following an accident), once the employee's medical condition is stabilized and the employee can give their consent to the collection (e.g., understand that a DOT collection is required, can sign the CCF), a urine specimen collected by this means should be obtained from that employee. Procedures similar to those listed below may be used when an external urine bag is involved.

External Urine Bag

The following procedures should be used in the collection of a urine specimen from an employee who has a medical condition requiring an indwelling catheter or excretion of urine into an external bag:

- The urine specimen should be freshly voided.
- An employee with an indwelling catheter may urinate directly into a collection container.
- In the case of an employee with an external bag:
    - The employee should be asked to empty their bag in the privacy of a bathroom,
    - Show the empty bag to the collector and
    - Then drink sufficient fluids at the collection site to provide 45 mL of urine, which can be subsequently poured by the employee from the bag into a collection container in the privacy of a bathroom.
    - In this case, the temperature of the specimen should not be a critical factor. If the specimen temperature is out of range, a direct observation collection should not necessarily be required because of the nature of the collection. You should be aware of the potential embarrassment that this type of collection can cause the employee and should conduct the collection with appropriate decorum.

This procedure should not have to be done in a medical environment/health clinic or by a collector of the same sex, although the collector may try to accommodate the employee (e.g., conduct the collection at a medical facility, have the same sex collector) if the employee requests this, and it should not significantly delay the collection process.

If the employer is aware of this situation prior to the actual collection (e.g., because the

employee had previously expressed a desire to provide the specimen in a medical setting, requested a same sex collector, told the employer about the medical condition and its impact on urine collection for drug testing), the employer (collection site) may establish or modify procedures as needed to permit the employee to provide a specimen in a way consistent with the employee's privacy while still meeting regulatory requirements.

In the case of a collection based on a post-accident or reasonable suspicion requirement, the collector may attempt to honor the employee's request (for the collection to be conducted in a medical setting or for the collector to be the same sex) if the collection can be accomplished within a reasonable time frame.

The above scenario assumes that the employee's medical condition does not reduce or completely preclude renal output, and that the employee can produce normal amounts of urine that are excreted into an external bag. Therefore, an employee with this or similar medical conditions should be subject to the same testing requirements (e.g., pre-employment, random) and to the "shy bladder" protocol (three hours and 40 ounces of fluids) as an employee with no medical condition.

If an employee who normally voids in this manner declines to provide a urine specimen under these conditions, immediately notify the DER of the refusal event so the employer can make the refusal determination [***See Section 12*** of these Guidelines].

SECTION 14: 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. There is **one exception**: when you learn that a directly observed collection should have been conducted but was not, you must notify the employer to direct the employee to return for an immediate recollection under direct observation.

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

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 on 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 on which 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 that 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 the 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 15: 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 copy together with the collector copy for 30 days. This is in the event the MRO requests another copy.

SECTION 16: QUESTIONS AND ANSWERS

1) Can an employer or training entity 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 does not possess training documents, they are in violation of Part 40 (§ 40.33).

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 § 40.33).

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, C/TPA) designated by the employer is responsible for notifying the collection site of the error (see § 40.33).

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

If the laboratory finds there is an insufficient amount of urine 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 urine 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 urine. 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 actual 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 must notify the DER that the employee has not reported for testing (see § 40.61).

For a pre-employment test, it is not 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 cup 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/Employer 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 that 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 urine 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, the collector is limited to conducting a collection for only one employee at a time. However, during the 3-hour waiting period that an employee is consuming fluids (shy bladder), the collector may conduct a collection for another employee. In this case, the employee with the shy bladder 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 (excluding directly observed collections)?

While the employee must be told to remove outer articles of clothing (e.g., coats, jackets), the employee must not be asked to remove other articles of clothing, such as shirts, pants, dresses, or undergarments. Additionally, the employee **must not** be requested or required to remove all clothing or change into 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 have to be removed unless the collector has a reason to suspect that the employee has something in the boots that 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 2.
- Place the seals from the second CCF perpendicular to the original seals to avoid obscuring information on the original seals. 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 need to be under the employee's direct observation, the employee may 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) What does the collector do with any leftover urine?

According to § 40.71(b)(9), any urine specimen left over in the collection container after both specimen bottles have been appropriately filled and sealed **must be discarded**. Excess urine may be used to conduct clinical tests (e.g., protein, glucose) **if** the collection was conducted in conjunction with a physical examination required by a DOT agency regulation.

> No further testing (e.g., adulteration testing, DNA, additional drugs) may be conducted on this excess urine, and the employee has no legal right to demand that the excess urine be turned over to the employee.

15) How should a shy bladder 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 shy bladder collection (e.g., because of a shift change during the three-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 3-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 shy bladder procedure).

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

If the collection site is closing and the employee has not completed the shy bladder process, the collector/collection site should make every effort to ensure the employee is afforded up to three hours for a "shy bladder" 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 three-hour period due to the collection site closing before it ends, the collection site should not conduct testing within that time period.

17) 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 must request another faxed copy or a hard copy.

18) What should the collector do if they note conduct that clearly indicates an attempt to substitute or adulterate a specimen?

The collector must pay close attention to the employee during the entire collection process to note any conduct that clearly indicates an attempt to substitute or adulterate a specimen. If the collector detects such conduct, the collector must complete the collection and immediately begin a new collection under direct observation using a second CCF and a new kit (see § 40.65(c)).

The collector should provide an appropriate comment on the "Remarks" line in Step 2 on the first CCF and second CCF, indicating that this is the first of two or second of two (i.e., 1 of 2, 2 of 2) collections, the specimen ID numbers of the first and second CCF, the reason for the second collection and that the second collection was conducted under direct observation (check the appropriate box in Step 2 of the second CCF). This will ensure that the laboratory and the MRO know that two separate specimens are being submitted for testing, with the first one possibly being adulterated or substituted. Additionally, the collector must inform the collection site supervisor and the DER that a collection took place under direct observation and the reason for having done so.

APPENDIX A – SUGGESTED FORMAT: "Documenting Collector Qualification Training Required by 49 CFR Section 40.33"

---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 a urine collector---

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

was trained in accordance with 49 CFR § 40.33, by: _____
Printed name & signature of the Trainer

to meet the qualification requirements of 49 CFR § 40.33.

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 Urine Specimen Collection Procedures Guidelines," _____
  - applicable DOT agency regulations for whom the collector will perform DOT-regulated collections; _____
  - other materials are available from the Office of Drug & Alcohol Policy & 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 "shy bladder" 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] [1] The person(s) conducting the training is qualified under 49 CFR § 40.33(c)(2).

Initial Proficiency Demonstration

- After the completion of the qualification training noted above, 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 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 five mock collections have included the following collection scenarios:
        - two uneventful collections; _____ (Monitor); _____ (Collector)
        - one insufficient quantity; _____ (Monitor); _____ (Collector)
        - one temperature out of range; _____ (Monitor); _____ (Collector)
        - one 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.

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[2] The person(s) monitoring the error-free mock collections is qualified under 49 CFR § 40.33(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 should be included.

APPENDIX B – URINE COLLECTION SITE SECURITY AND INTEGRITY

DOT's 10 Steps to Collection Site Security and Integrity
Office of Drug and Alcohol Policy and Compliance
U.S. Department of Transportation

1. Pay careful attention to employees throughout the collection process.

2. Ensure that there is no unauthorized access into the collection areas and that undetected access (e.g., through a door not in view) is not possible.

3. Make sure that employees show proper picture ID.

4. Make sure employees empty pockets; remove outer garments (e.g., coveralls, jacket, coat, hat); leave briefcases, purses, and bags behind; and wash their hands.

5. Always maintain personal control of the specimen and CCF during the collection.

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

7. Ensure that the water in the toilet and tank (if applicable) has bluing (coloring) agent in it. Tape or otherwise secure shut any movable toilet tank top or put bluing in the tank.

8. Ensure that no soap, disinfectants, cleaning agents, or other possible adulterants are present.

9. Inspect the site to ensure that no foreign or unauthorized substances are present.

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

APPENDIX C – DOT STANDARDS FOR URINE COLLECTION KITS

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

   b. Must have graduated volume markings clearly noting levels of 45 mL and above.

   c. Must have a temperature strip providing graduated temperature readings 32-38 º C / 90-100 º F that is affixed or can be affixed at a proper level on the outside of the collection container. Other methodologies (e.g., temperature device built into the wall of the container) are acceptable, provided the temperature measurement is accurate and such that there is no potential for contamination of the specimen.

   d. Must be individually wrapped in a sealed plastic bag or shrink wrapping; or must have a peelable, sealed lid or other easily visible tamper-evident system.

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

2. **Plastic Specimen Bottles**
   a. Each bottle must be large enough to hold at least 35 mL; or alternatively, they may be two distinct sizes of specimen bottles provided that the bottle designed to hold the primary specimen holds at least 35 mL of urine and the bottle designed to hold the split specimen holds at least 20 mL.

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

   c. Must have markings clearly indicating the appropriate levels (30 mL for the primary specimen and 15 mL for the split) of urine that must be poured into the bottles.

   d. Must be designed so that the required tamper-evident bottle seals made available on the CCF fit with no damage to the seal when the employee initials it or with the chance that the seal overlap would conceal printed information.

   e. Must be wrapped (with caps) together in a sealed plastic bag or shrink wrapping separate from the collection container; or must be wrapped (with cap) individually in sealed plastic bags or shrink wrapping; or must have peelable, sealed lid or other easily visible tamper-evident system.

   f. Plastic material must be leach resistant.

3. **Leak-resistant Plastic Bag**
   a) Must have two sealable compartments or pouches which are leak-resistant; one large enough to hold two specimen bottles and the other large enough to hold the CCF paperwork.
   b) The sealing methodology must be such that once the compartments are sealed, any tampering or attempts to open either compartment will be evident.

4. **Absorbent material**
   a) Each kit must contain enough absorbent material to absorb the entire contents of both specimen bottles. Absorbent material must be designed to fit inside the leak-resistant plastic bag pouch into which the specimen bottles are placed.

5. **Shipping Container**
   a. Must be designed to adequately protect the specimen bottles from shipment damage in the transport of specimens from the collection site to the laboratory (e.g., standard courier box, small cardboard box, plastic container).

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

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

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APPENDIX D – DIRECT OBSERVATION PROCEDURES FOR URINE COLLECTIONS

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

1. DOT's 49 CFR Part 40 directly observed collections are authorized and required only when:

   a) **The employee attempts to tamper with their specimen at the collection site.**
   b) **The specimen temperature is outside the acceptable range.**
   c) **The specimen shows signs of tampering ~ unusual color / odor / characteristic; or**
   d) **The collector finds an item in the employee's pockets or wallet which appears to be brought into the site to contaminate a specimen; or**
   e) **The collector notes conduct suggesting tampering.**
   f) **The Medical Review Officer (MRO) orders the direct observation because:**
      1. **The employee has no legitimate medical reason for certain atypical laboratory results; or**
      2. **The employee's positive or refusal [adulterated/substituted] test result had to be cancelled because the split specimen test could not be performed (for example, the split was not collected).**
   g) **The test is a Follow-Up test or a Return-to-Duty test.**

2. The observer must be the same sex as the employee.

3. If the collector is not the observer, the collector must instruct the observer about the procedures for checking the employee for prosthetic or other devices designed to carry "clean" urine and urine substitutes AND for watching the employee urinate into the collection container.

   a) **The observer requests the employee to raise their shirt, blouse or dress/skirt, as appropriate, above the waist, just above the navel; and lower clothing and underpants to mid-thigh and show the observer, by turning around, that the employee does not have such a device.**

   b) ***If The Employee Has A Device*: The observer immediately notifies the collector; the collector stops the collection; and the collector thoroughly documents the circumstances surrounding the event in the remarks section of CCF. The collector notifies the DER/Employer. This is a refusal to test.**

   c) ***If The Employee Does Not Have A Device*: The employee is permitted to return clothing to its proper position for the observed collection. The observer must watch the urine go from the employee's body into the collection container. The observer must watch as the employee takes the specimen to the collector. The collector then completes the collection process.**

4. Failure of the employee to permit any part of the direct observation procedure is a refusal to test.

APPENDIX E – DOT OPERATING ADMINISTRATION RULES

49 CFR Part 40 (§ 40.33(a)) states that collectors must be knowledgeable about the DOT agency regulations applicable to the employers for whom the collectors conduct urine specimen collections. The following is a list of regulations that 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 DOT 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.

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U.S. Department of Transportation
Office of the Secretary

Office of Drug & Alcohol Policy & Compliance

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

202.366.3784

http://www.transportation.gov/odapc

ODAPCwebmail@dot.gov

Changes from the previous version [January 2018]:

- Cover page: updated title to "DOT Urine Specimen Collection Procedures Guidelines" to align with the title referenced in Part 40.
- Page 3: updated the "Introduction."
- Page 4: added a new section with a general overview of oral fluid collections and throughout the document as necessary
- Page 9: added language to clarify urine collector training requirements
- Page 14: added language clarifying what to do if there is a problem printing the authoritative copy of the CCF.
- Page 16: added language clarifying what is an acceptable ID
- Page 20: added hand sanitizer as an option when washing hands is required
- Page 31: updated directly observed procedures
- Page 36: edited a section/table on "Refusal to Test."
- New Appendix A – added a suggested format for documenting collector training

The following updates occur on multiple pages throughout the document:

- Website addresses/hyperlinks as necessary
- Language to reflect EO 14168
- Procedures for new CCF
- When to switch to an oral fluid collection
- Add graphics of sections of the CCF

[back cover]