§ 40.49
reject the specimen for testing or for an MRO to cancel the result.
(2) The use of the non-Federal form is a “correctable flaw.” As an MRO, to correct the problem you must follow the procedures of §40.205(b)(2).
[65 FR 79526, Dec. 19, 2000, as amended at 66 FR 41950, Aug. 9, 2001]
§ 40.49 What materials are used to collect urine specimens?
For each DOT drug test, you must use a collection kit meeting the requirements of Appendix A of this part.

§ 40.51 What materials are used to send urine specimens to the laboratory?
(a) Except as provided in paragraph (b) of this section, you must use a shipping container that adequately protects the specimen bottles from shipment damage in the transport of specimens from the collection site to the laboratory.
(b) You are not required to use a shipping container if a laboratory courier hand-delivers the specimens from the collection site to the laboratory.

Subpart E—Urine Specimen Collections
§ 40.61 What are the preliminary steps in the collection process?
As the collector, you must take the following steps before actually beginning a collection:
(a) When a specific time for an employee’s test has been scheduled, or the collection site is at the employee’s work site, and the employee does not appear at the collection site at the scheduled time, contact the DER to determine the appropriate interval within which the DER has determined the employee is authorized to arrive. If the employee’s arrival is delayed beyond that time, you must notify the DER that the employee has not reported for testing. In a situation where a C/TPA has notified an owner/operator or other individual employee to report for testing and the employee does not appear, the C/TPA must notify the employee that he or she has refused to test (see §40.191(a)(1)).
(b) Ensure that, when the employee enters the collection site, you begin the testing process without undue delay. For example, you must not wait because the employee says he or she is not ready or is unable to urinate or because an authorized employer or employee representative is delayed in arriving.
(1) If the employee is also going to take a DOT alcohol test, you must, to the greatest extent practicable, ensure that the alcohol test is completed before the urine collection process begins.
Example to Paragraph (b)(1): An employee enters the test site for both a drug and an alcohol test. Normally, the collector would wait until the BAT had completed the alcohol test process before beginning the drug test process. However, there are some situations in which an exception to this normal practice would be reasonable. One such situation might be if several people were waiting for the BAT to conduct alcohol tests, but a drug testing collector in the same facility were free. Someone waiting might be able to complete a drug test without unduly delaying his or her alcohol test. Collectors and BATs should work together, however, to ensure that post-accident and reasonable suspicion alcohol tests happen as soon as possible (e.g., by moving the employee to the head of the line for alcohol tests).
(2) If the employee needs medical attention (e.g., an injured employee in an emergency medical facility who is required to have a post-accident test), do not delay this treatment to collect a specimen.
(3) You must not collect, by catheterization or other means, urine from an unconscious employee to conduct a drug test under this part. Nor may you catheterize a conscious employee. However, you must inform an employee who normally voids through self-catheterization that the employee is required to provide a specimen in that manner.
(4) If, as an employee, you normally void through self-catheterization, and decline to do so, this constitutes a refusal to test.
(c) Require the employee to provide positive identification. You must see a photo ID issued by the employer (other than in the case of an owner-operator or other self-employed individual) or a Federal, state, or local government (e.g., a driver’s license). You may not
accept faxes or photocopies of identification. Positive identification by an employer representative (not a co-worker or another employee being tested) is also acceptable. If the employee cannot produce positive identification, you must contact a DER to verify the identity of the employee.

(d) If the employee asks, provide your identification to the employee. Your identification must include your name and your employer’s name, but does not have to include your picture, address, or telephone number.

(e) Explain the basic collection procedure to the employee, including showing the employee the instructions on the back of the CCF.

(f) Direct the employee to remove outer clothing (e.g., coveralls, jacket, coat, hat) that could be used to conceal items or substances that could be used to tamper with a specimen. You must also direct the employee to leave these garments and any briefcase, purse, or other personal belongings with you or in a mutually agreeable location. You must advise the employee that failure to comply with your directions constitutes a refusal to test.

(1) If the employee asks for a receipt for any belongings left with you, you must provide one.

(2) You must allow the employee to keep his or her wallet.

(3) You must not ask the employee to remove other clothing (e.g., shirts, pants, dresses, underwear), to remove all clothing, or to change into a hospital or examination gown (unless the urine collection is being accomplished simultaneously with a DOT agency-authorized medical examination).

(4) You must direct the employee to empty his or her pockets and display the items in them to ensure that no items are present which could be used to adulterate the specimen. If nothing is there that can be used to adulterate a specimen, the employee can place the items back into his or her pockets. As the employee, you must allow the collector to make this observation.

(5) If, in your duties under paragraph (f)(4) of this section, you find any material that could be used to tamper with a specimen, you must:

(i) Determine if the material appears to be brought to the collection site with the intent to alter the specimen, and, if it is, conduct a directly observed collection using direct observation procedures (see §40.67); or

(ii) Determine if the material appears to be inadvertently brought to the collection site (e.g., eye drops), secure and maintain it until the collection process is completed and conduct a normal (i.e., unobserved) collection.

(g) You must instruct the employee not to list medications that he or she is currently taking on the CCF. (The employee may make notes of medications on the back of the employee copy of the form for his or her own convenience, but these notes must not be transmitted to anyone else.)

§ 40.63 What steps does the collector take in the collection process before the employee provides a urine specimen?

As the collector, you must take the following steps before the employee provides the urine specimen:

(a) Complete Step 1 of the CCF.

(b) Instruct the employee to wash and dry his or her hands at this time. You must tell the employee not to wash his or her hands again until after delivering the specimen to you. You must not give the employee any further access to water or other materials that could be used to adulterate or dilute a specimen.

(c) Select, or allow the employee to select, an individually wrapped or sealed collection container from collection kit materials. Either you or the employee, with both of you present, must unwrap or break the seal of the collection container. You must not unwrap or break the seal on any specimen bottle at this time. You must not allow the employee to take anything from the collection kit into the room used for urination except the collection container.

(d) Direct the employee to go into the room used for urination, provide a specimen of at least 45 mL, not flush the toilet, and return to you with the specimen as soon as the employee has completed the void.

(1) Except in the case of an observed or a monitored collection (see §§ 40.67 and 40.69), neither you nor anyone else
may go into the room with the employee.

(2) As the collector, you may set a reasonable time limit for voiding.

(e) You must pay careful attention to the employee during the entire collection process to note any conduct that clearly indicates an attempt to tamper with a specimen (e.g., substitute urine in plain view or an attempt to bring into the collection site an adulterant or urine substitute). If you detect such conduct, you must require that a collection take place immediately under direct observation (see §40.67 ) and note the conduct and the fact that the collection was observed in the “Remarks” line of the CCF (Step 2). You must also, as soon as possible, inform the DER and collection site supervisor that a collection took place under direct observation and the reason for doing so.

§ 40.65 What does the collector check for when the employee presents a specimen?

As a collector, you must check the following when the employee gives you the collection container:

(a) Sufficiency of specimen. You must check to ensure that the specimen contains at least 45 mL of urine.

(1) If it does not, you must follow “shy bladder” procedures (see §40.193(b)).

(2) When you follow “shy bladder” procedures, you must discard the original specimen, unless another problem (i.e., temperature out of range, signs of tampering) also exists.

(3) You are never permitted to combine urine collected from separate voids to create a specimen.

(4) You must discard any excess urine.

(b) Temperature. You must check the temperature of the specimen no later than four minutes after the employee has given you the specimen.

(1) The acceptable temperature range is 22–38 °C (90–100 °F).

(2) You must determine the temperature of the specimen by reading the temperature strip attached to the collection container.

(3) If the specimen temperature is within the acceptable range, you must mark the “Yes” box on the CCF (Step 2).

(4) If the specimen temperature is outside the acceptable range, you must mark the “No” box and enter in the “Remarks” line (Step 2) your findings about the temperature.

(5) If the specimen temperature is outside the acceptable range, you must immediately conduct a new collection using direct observation procedures (see §40.67).

(6) In a case where a specimen is collected under direct observation because of the temperature being out of range, you must process both the original specimen and the specimen collected using direct observation and send the two sets of specimens to the laboratory. This is true even in a case in which the original specimen has insufficient volume but the temperature is out of range. You must also, as soon as possible, inform the DER and collection site supervisor that a collection took place under direct observation and the reason for doing so.

(7) In a case where the employee refuses to provide another specimen (see §40.191(a)(3)) or refuses to provide another specimen under direct observation (see §40.191(a)(4)), you must notify the DER. As soon as you have notified the DER, you must discard any specimen the employee has provided previously during the collection procedure.

(c) Signs of tampering. You must inspect the specimen for unusual color, presence of foreign objects or material, or other signs of tampering (e.g., if you notice any unusual odor).

(1) If it is apparent from this inspection that the employee has tampered with the specimen (e.g., blue dye in the specimen, excessive foaming when shaken, smell of bleach), you must immediately conduct a new collection using direct observation procedures (see §40.67).

(2) In a case where a specimen is collected under direct observation because of showing signs of tampering, you must process both the original specimen and the specimen collected using direct observation and send the two sets of specimens to the laboratory. This is true even in a case in which the original specimen has insufficient volume but it shows signs of tampering.
§ 40.67 When and how is a directly observed collection conducted?

(a) As an employer, you must direct an immediate collection under direct observation with no advance notice to the employee, if:

(1) The laboratory reported to the MRO that a specimen is invalid, and the MRO reported to you that there was not an adequate medical explanation for the result;

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

(3) The laboratory reported to the MRO that the specimen was negative-dilute with a creatinine concentration greater than or equal to 2 mg/dL but less than or equal to 5 mg/dL, and the MRO reported the specimen to you as negative-dilute and that a second collection must take place under direct observation (see § 40.197(b)(1)).

(b) As an employer, you must direct a collection under direct observation of an employee if the drug test is a return-to-duty test or a follow-up test.

(c) As a collector, you must immediately conduct a collection under direct observation if:

(1) You are directed by the DER to do so (see paragraphs (a) and (b) of this section); or

(2) You observed materials brought to the collection site or the employee’s conduct clearly indicates an attempt to tamper with a specimen (see §§ 40.61(f)(5)(1) and 40.63(e)); or

(3) The temperature on the original specimen was out of range (see § 40.65(b)(5)); or (4) The original specimen appeared to have been tampered with (see § 40.65(c)(1)).

(d)(1) As the employer, you must explain to the employee the reason for a directly observed collection under paragraph (a) or (b) of this section.

(2) As the collector, you must explain to the employee the reason, if known, under this part for a directly observed collection under paragraphs (c)(1) through (3) of this section.

(e) As the collector, you must complete a new CCF for the directly observed collection.

(1) You must mark the “reason for test” block (Step 1) the same as for the first collection.

(2) You must check the “Observed, (Enter Remark)” box and enter the reason (see § 40.67(b)) in the “Remarks” line (Step 2).

(f) In a case where two sets of specimens are being sent to the laboratory because of suspected tampering with the specimen at the collection site, enter on the “Remarks” line of the CCF (Step 2) for each specimen a notation to this effect (e.g., collection 1 of 2, or 2 of 2) and the specimen ID number of the other specimen.

(g) As the collector, you must ensure that the observer is the same gender as the employee. You must never permit an opposite gender person to act as the observer. The observer can be a different person from the collector and need not be a qualified collector.

(h) As the collector, if someone else is to observe the collection (e.g., in order to ensure a same gender observer), you must verbally instruct that person to follow procedures at paragraphs (i) and (j) of this section. If you, the collector, are the observer, you too must follow these procedures.

(i) As the observer, you must request the employee to raise his or her shirt, blouse, or dress/skirt, as appropriate, above the waist; and lower clothing and underpants to show you, by turning around, that they do not have a prosthetic device. After you have determined that the employee does not have such a device, you may permit the employee to return clothing to its proper position for observed urination.

(j) As the observer, you must watch the employee urinate into the collection container. Specifically, you are to
§ 40.69 How is a monitored collection conducted?

(a) As the collector, you must secure the room being used for the monitored collection so that no one except the employee and the monitor can enter it until after the collection has been completed.

(b) As the collector, you must ensure that the monitor is the same gender as the employee, unless the monitor is a medical professional (e.g., nurse, doctor, physician’s assistant, technologist, or technician licensed or certified to practice in the jurisdiction in which the collection takes place). The monitor can be a different person from the collector and need not be a qualified collector.

(c) As the collector, if someone else is to monitor the collection (e.g., in order to ensure a same-gender monitor), you must verbally instruct that person to follow the procedures of paragraphs (d) and (e) of this section. If you, the collector, are the monitor, you must follow these procedures.

(d) As the monitor, you must not watch the employee urinate into the collection container. If you hear sounds or make other observations indicating an attempt to tamper with a specimen, there must be an additional collection under direct observation (see §§ 40.63(e), 40.65(c), and 40.67(b)).

(e) As the monitor, you must ensure that the employee takes the collection container directly to the collector as soon as the employee has exited the enclosure.

(f) As the collector, when someone else has acted as the monitor, you must note that person’s name in the “Remarks” line of the CCF (Step 2).

(g) As the employee being tested, if you decline to permit a collection authorized under this section to be monitored, it is a refusal to test.

§ 40.71 How does the collector prepare the specimens?

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

(b) As the collector, you must take the following steps, in order, after the employee brings the urine specimen to you. You must take these steps in the presence of the employee.

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

2. You, not the employee, must first pour at least 30 mL of urine from the collection container into one specimen bottle, to be used for the primary specimen.

3. You, not the employee, must then pour at least 15 mL of urine from the collection container into the second specimen bottle to be used for the split specimen.

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

5. You, not the employee, must seal the bottles by placing the tamper-evident bottle seals over the bottle caps/lids and down the sides of the bottles.

6. You, not the employee, must then write the date on the tamper-evident bottle seals.

7. You must then ensure that the employee initials the tamper-evident bottle seals for the purpose of certifying that the bottles contain the
specimens he or she provided. If the employee fails or refuses to do so, you must note this in the “Remarks” line of the CCF (Step 2) and complete the collection process.

(8) You must discard any urine left over in the collection container after both specimen bottles have been appropriately filled and sealed. There is one exception to this requirement: you may use excess urine to conduct clinical tests (e.g., protein, glucose) if the collection was conducted in conjunction with a physical examination required by a DOT agency regulation. Neither you nor anyone else may conduct further testing (such as adulteration testing) on this excess urine and the employee has no legal right to demand that the excess urine be turned over to the employee.

§ 40.73 How is the collection process completed?

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

(1) Direct the employee to read and sign the certification statement on Copy 2 (Step 5) of the CCF and provide date of birth, printed name, and day and evening contact telephone numbers. If the employee refuses to sign the CCF or to provide date of birth, printed name, or telephone numbers, you must note this in the “Remarks” line (Step 2) of the CCF, and complete the collection. If the employee refuses to fill out any information, you must, as a minimum, print the employee’s name in the appropriate place.

(2) Complete the chain of custody on the CCF (Step 4) by printing your name (note: you may pre-print your name), recording the time and date of the collection, signing the statement, and entering the name of the delivery service transferring the specimen to the laboratory.

(3) Ensure that all copies of the CCF are legible and complete.

(4) Remove Copy 5 of the CCF and give it to the employee.

(5) Place the specimen bottles and Copy 1 of the CCF in the appropriate pouches of the plastic bag.

(6) Secure both pouches of the plastic bag.

(7) Advise the employee that he or she may leave the collection site.

(8) To prepare the sealed plastic bag containing the specimens and CCF for shipment you must:

(i) Place the sealed plastic bag in a shipping container (e.g., standard courier box) designed to minimize the possibility of damage during shipment. (More than one sealed plastic bag can be placed into a single shipping container if you are doing multiple collections.)

(ii) Seal the container as appropriate.

(iii) If a laboratory courier hand-delivers the specimens from the collection site to the laboratory, prepare the sealed plastic bag for shipment as directed by the courier service.

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

(b) As a collector or collection site, you must ensure that each specimen you collect is shipped to a laboratory as quickly as possible, but in any case within 24 hours or during the next business day.

§ 40.81 What laboratories may be used for DOT drug testing?

(a) As a drug testing laboratory located in the U.S., you are permitted to participate in DOT drug testing only if you are certified by HHS under the National Laboratory Certification Program (NLCP) for all testing required under this part.

(b) As a drug testing laboratory located in Canada or Mexico which is not certified by HHS under the NLCP, you are permitted to participate in DOT drug testing only if: