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

(4) You must discard any excess urine.

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

(1) The acceptable temperature range is 32–38 °C/90–100 °F.

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

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

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

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

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

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

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

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

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

(3) In a case where the employee refuses to provide a specimen under direct observation (see § 40.191(a)(4)), you must discard any specimen the employee provided previously during the collection procedure. Then you must notify the DER as soon as practicable.

[65 FR 79526, Dec. 19, 2000, as amended at 66 FR 41950, Aug. 9, 2001; 88 FR 27641, May 2, 2023]

§ 40.67 When and how is a directly observed urine collection conducted?

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

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

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

(3) The laboratory reported to the MRO that the specimen was negative-dilute with a creatinine concentration greater than or equal to 2 mg/dL but less than or equal to 5 mg/dL, and the MRO reported the specimen to you as

negative-dilute and that a second collection must take place under direct observation (see § 40.197(b)(1)).

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

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

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

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

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

(3) The temperature on the original specimen was out of range (*see* § 40.65(b)(5));

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

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

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

(2) As the collector, you must explain to the employee the reason, if known, under this part for a directly observed collection.

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

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

(2) You must check the ''Observed, (Enter Remark)'' box and enter the reason (see paragraphs (c)(2) through (4) of this section) in the ''Remarks'' line (Step 2).

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

(g) As the collector, you must ensure that the observer is the same gender as the employee.

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

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

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

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

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

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

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

(j) As the observer, you must watch the employee urinate into the collection container. Specifically, you are to watch the urine go from the employee's body into the collection container.

(k) As the observer but not the collector, you must not take the collection container from the employee, but you must observe the specimen as the employee takes it to the collector.

(l) As the collector, when someone else has acted as the observer, you must include the observer's name in the ''Remarks'' line of the CCF (Step 2).

(m) As the employee, if you decline to allow a directly observed collection

required or permitted under this section to occur, this is a refusal to test.

(n) As a service agent, when you learn that a directly observed collection should have been collected but was not, you must inform the employer that it must direct the employee to have an immediate recollection under direct observation.

[65 FR 79526, Dec. 19, 2000, as amended at 66 FR 41950, Aug. 9, 2001; 68 FR 31626, May 28, 2003; 69 FR 64867, Nov. 9, 2004; 73 FR 35970, June 25, 2008; 73 FR 50223, Aug. 26, 2008; 73 FR 62910, Oct. 22, 2008; 73 FR 70284, Nov. 20, 2008; 74 FR 37952, July 30, 2009; 82 FR 52244, Nov. 13, 2017; 88 FR 27641, May 2, 2023]

§ 40.69 How is a monitored urine collection conducted?

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

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

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

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

(e) As the monitor, you must not watch the employee urinate into the collection container. If you hear sounds or make other observations indicating an attempt to tamper with a specimen, there must be an additional collection under direct observation. *See* §§ 40.63(e), 40.65(c), and 40.67(c)(2)(3)).

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

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

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

[65 FR 79526, Dec. 19, 2000, as amended at 66 FR 41951, Aug. 9, 2001; 88 FR 27641, May 2, 2023]

§ 40.71 How does the collector prepare the urine specimen?

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

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

(1) After the collection, check the box on the CCF (Step 2) indicating that this was a ''Urine'' and ''Split'' specimen collection.

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

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

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

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

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

(7) You must then ensure that the employee initials the tamper-evident bottle seals for the purpose of certifying that the bottles contain the specimens he or she provided. If the employee fails or refuses to do so, you