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way that disrupts the collection process, fail to wash hands after being directed to do so by the collector, fail to remove objects from mouth, fail to permit inspection of the oral cavity, or fail to complete a rinse when requested);

(9) For an observed urine collection, fail to follow the observer's instructions to raise your clothing above the waist, lower clothing and underpants, and to turn around to permit the observer to determine if you have any type of prosthetic or other device that could be used to interfere with the collection process;

(10) Possess or wear a prosthetic or other device that could be used to interfere with the collection process; or

(11) Admit to the collector or MRO that you adulterated or substituted the specimen.

(b) As an employee, if the MRO reports that you have a verified adulterated or substituted test result, you have refused to take a drug test.

(c) As an employee, if you refuse to take a drug test, you incur the consequences specified under DOT agency regulations for a violation of those DOT agency regulations. The consequences specified under DOT agency regulations for a refusal cannot be overturned or set aside by an arbitration, grievance, State court or other non-Federal forum that adjudicates the personnel decisions the employer has taken against the employee.

(d) As a collector or an MRO, when an employee refuses to participate in the part of the testing process in which you are involved, you must terminate the portion of the testing process in which you are involved, document the refusal on the CCF (including, in the case of the collector, printing the employee's name on Copy 2 of the CCF), immediately notify the DER by any means (e.g., telephone or secure fax machine) that ensures that the refusal notification is immediately received. As a referral physician (e.g., physician evaluating a "shy bladder" condition or a claim of a legitimate medical explanation in a validity testing situation), you must notify the MRO, who in turn will notify the DER.

(1) As the collector, you must note the actions that may constitute a re-

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

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

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

[65 FR 79526, Dec. 19, 2000, as amended at 66 FR 41953, Aug. 9, 2001; 68 FR 31626, May 28, 2003; 71 FR 49384, Aug. 23, 2006; 73 FR 35974, June 25, 2008; 75 FR 59108, Sept. 27, 2010; 88 FR 27647, May 2, 2023; 89 FR 51983, June 21, 2024]

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

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

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

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

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

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

(i) Discard the insufficient specimen, except where the insufficient specimen was out of temperature range or showed evidence of adulteration or tampering (*see* § 40.65(b) and (c)).

(ii) Urge the employee to drink up to 40 ounces of fluid, distributed reasonably through a period of up to three hours, or until the individual has provided a sufficient urine specimen, whichever occurs first. It is not a refusal to test if the employee declines to drink. Document on the Remarks line of the CCF (Step 2), and inform the employee of the time at which the three-hour period begins and ends.

(iii) If the employee refuses to make the attempt to provide a new urine specimen or leaves the collection site before the collection process is complete, you must discontinue the collection, note that fact on the "Remarks" line of the CCF (Step 2), and immediately notify the DER of the conduct as provided in § 40.191(e)(1); the employer decides whether the situation is deemed to be a refusal.

(iv) If the employee has not provided a sufficient specimen within three hours of the first unsuccessful attempt to provide the specimen, you must discontinue the collection, note the fact on the "Remarks" line of the CCF (Step 2), and immediately notify the DER. You must also discard any specimen the employee previously provided, including any specimen that is "out of temperature range" or shows signs of tampering. In the remarks section of the CCF that you will distribute to the MRO and DER, note the fact that the employee provided an "out of temperature range specimen" or "specimen that shows signs of tampering" and that it was discarded because the em-

ployee did not provide a second sufficient specimen.

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

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

(ii) If the employee has not provided a sufficient specimen within one hour of the first unsuccessful attempt to provide the specimen, you must discontinue the collection, note the fact on the "Remarks" line of the CCF (Step 2), and immediately notify the DER.

(3) Send Copy 2 of the CCF to the MRO and Copy 4 to the DER. You must send or fax these copies to the MRO and DER within 24 hours or the next business day.

(c) As the DER, if the collector informs you that the employee has not provided a sufficient amount of specimen (*see* paragraph (b) of this section), you must, after consulting with the MRO, direct the employee to obtain, within five days, an evaluation from a licensed physician, acceptable to the MRO, who has expertise in the medical issues raised by the employee's failure to provide a urine (*see* paragraph (b)(1) of this section) or oral fluid (*see* paragraph (b)(2) of this section) sufficient specimen, but not both. The evaluation and MRO determination required by this section only applies to the oral fluid or the urine insufficient specimen that was the final methodology at the

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collection site. (The MRO may perform this evaluation if the MRO has appropriate expertise.)

(1) As the MRO, if another physician will perform the evaluation, you must provide the other physician with the following information and instructions:

(i) That the employee was required to take a DOT drug test, but was unable to provide a sufficient amount of specimen to complete the test;

(ii) The consequences of the appropriate DOT agency regulation for refusing to take the required drug test;

(iii) That the referral physician must agree to follow the requirements of paragraphs (d) through (g) of this section.

(2) [Reserved]

(d) As the referral physician conducting this evaluation, you must recommend that the MRO make one of the following determinations:

(1) A medical condition has, or with a high degree of probability could have, precluded the employee from providing a sufficient amount of specimen. As the MRO, if you accept this recommendation, you must:

(i) Check “Test Cancelled” (Step 6) on the CCF; and

(ii) Sign and date the CCF.

(2) There is not an adequate basis for determining that a medical condition has, or with a high degree of probability could have, precluded the employee from providing a sufficient amount of specimen. As the MRO, if you accept this recommendation, you must:

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

(ii) Sign and date the CCF.

(e) For purposes of this paragraph, a medical condition includes an ascertainable physiological condition (*e.g.*, a urinary system dysfunction in the case of a urine test or autoimmune disorder in the case of an oral fluid test), or a medically documented pre-existing psychological disorder, but does not include unsupported assertions of “situational anxiety” or dehydration.

(f) As the referral physician making the evaluation, after completing your evaluation, you must provide a written

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statement of your recommendations and the basis for them to the MRO. You must not include in this statement detailed information on the employee’s medical condition beyond what is necessary to explain your conclusion.

(g) If, as the referral physician making this evaluation in the case of a pre-employment, return-to-duty, or follow-up test, you determine that the employee’s medical condition is a serious and permanent or long-term disability that is highly likely to prevent the employee from providing a sufficient amount of specimen for a very long or indefinite period of time, you must set forth your determination and the reasons for it in your written statement to the MRO. As the MRO, upon receiving such a report, you must follow the requirements of § 40.195, where applicable.

(h) As the MRO, you must seriously consider and assess the referral physician’s recommendations in making your determination about whether the employee has a medical condition that has, or with a high degree of probability could have, precluded the employee from providing a sufficient amount of specimen. You must report your determination to the DER in writing as soon as you make it.

(i) As the employer, when you receive a report from the MRO indicating that a test is cancelled as provided in paragraph (d)(1) of this section, you take no further action with respect to the employee. If the test reason was ‘random’, the employee remains in the random testing pool.

[88 FR 27647, May 2, 2023]

§ 40.195 What happens when an individual is unable to provide a sufficient amount of specimen for a pre-employment, follow-up, or return-to-duty test because of a permanent or long-term medical condition?

(a) This section concerns a situation in which an employee has a medical condition that precludes him or her from providing a sufficient specimen for a pre-employment follow-up or return-to-duty test and the condition involves a permanent or long-term disability. As the MRO in this situation, you must do the following:

(1) You must determine if there is clinical evidence that the individual is