Step 4 of the CCF. Since the collector will use one oral fluid device that will collect a single specimen, which is then subdivided in the presence of the donor, only one entry in Step 4 is to be made for the device expiration date.

(6) The collector must instruct the employee to use hand sanitizer or wash and dry his or her hands.

(e) To the greatest extent practicable, the collector must keep the employee's unwrapped collection device within view of both the collector and the employee, between the time the employee has provided a specimen and the specimen is sealed.

[88 FR 27642, May 2, 2023]

§ 40.73 How is an oral fluid specimen collected?

(a) The collector must be present and maintain visual contact with the employee during the procedures outlined in this section.

(b) The collector must note any unusual behavior or appearance of the employee on the CCF. If the collector detects any conduct that clearly indicates an attempt to tamper with a specimen (*e.g.*, an attempt to bring into the collection site an adulterant or oral fluid substitute), the collector must terminate the collection and report the information to the DER so that the employer can decide whether to deem the situation a refusal.

(c) The employee and collector must complete the specimen collection in accordance with the manufacturer's instructions for the collection device.

(1) Under the observation of the collector, the employee is responsible for positioning the specimen collection device for collection.

(2) The collector must ensure the collection is performed correctly (*i.e.*, using the oral fluid device in the manner described by its manufacturer), that the collection device is working properly, and that a sufficient specimen volume is collected.

(3) If the employee states that he or she is unable to provide an oral fluid specimen or provides an insufficient specimen during the collection process, the collector must continue to make one attempt to collect, after an insufficient specimen, the collector follows the procedure in § 40.193.

(4) The collector must inspect the specimen for unusual color, presence of foreign objects or material, or other signs of tampering. If it is apparent from this inspection that the employee has tampered with the specimen, the collector must conduct a new collection.

(i) Document any unusual characteristics referenced above in the Remarks section of the CCF.

(ii) Proceed with obtaining the new oral fluid specimen from the donor. Note on the new CCF that this is another collection for the same testing event (*i.e.*, Document in the remarks section that this is Specimen 2 of 2 and include the Specimen ID number of the other specimen). Make the same notation on the CCF of the suspect specimen.

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§ 40.74 How does the collector prepare the oral fluid specimens?

(a) The collector follows the manufacturer's instructions to package the split specimen collections.

(b) A volume of at least 1 mL of undiluted (neat) oral fluid is collected for the specimen designated as ''Bottle A'', and a volume of at least 1 mL of undiluted (neat) oral fluid is collected for the specimen designated as ''Bottle B'', or an otherwise sufficient amount of oral fluid is collected to permit an HHS-certified laboratory to analyze the specimen(s).

(c) In the presence of the employee, the collector places a tamper-evident seal from the CCF over the cap of each specimen container, taking care not to obstruct the expiration date on the collection containers. The collector must record the date of the collection on the tamper-evident seals, after they are affixed to the specimen containers.

(d) The collector instructs the employee to initial the tamper-evident seals on each specimen container. If the employee declines to do so, the collector must note this in the ''Remarks'' line of the CCF (Step 2) and complete the collection process.

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