Urine Collections Interview Questions

Chillicothe Transit System

Tammy Bochard DAPM 740-773-1211
Melissa Davis, ADENA Health System
Robbie Sarles RLS and Associates, Inc.
Terri Paige RLS and Associates, Inc.

Ohio Department of Transportation

February 25, 2015

#	Question	Finding	Regulation	Action Item
1	WERE THE NORMAL PREPARATORY SPECIMEN COLLECTION PROCEDURES FOLLOWED CORRECTLY AND COMPLETELY?			
2	Photo identification required?	Yes	Section 40.61(c) states: "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."	None
3	Was consent or release - giving the collection site or its personnel indemnification - required for testing to be performed?	No	Section 40.355(a) states: "Do not require an employee to sign a consent, release, waiver of liability, or indemnification agreement with respect to any part of the drug or alcohol testing process covered by this part (including, but not limited to, collections, laboratory testing, MRO, and SAP services). No one may do so on behalf of a service agent."	None

#	Question	Finding	Regulation	Action Item
4	Directed to remove any outer garments (e.g., jacket, coat, hat) and to leave personal belongings such as purses and briefcases with the outer garments?	Yes.	Section 40.61(f) states: "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. Also direct the employee to leave these garments and any briefcase, purse, or other personal belongings with you or in a mutually agreed upon location. Advise the employee that failure to comply with your directions constitutes a refusal to test."	None
5	Directed to empty pockets and display the contents?	Yes, but didn't ask to check pockets of sweater being worn.	Section 40.61(f)(4) states: "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. The employee must allow the collector to make this observation."	The collector must provide a signed statement certifying that she has read and fully understands the requirements of 49 CFR Part 40.61 (f)(4). This statement must also include an explanation from the DAPM of how this requirement will be met moving forward.
6	Is the employee allowed to keep his/her wallet, or is the wallet maintained in a sufficiently secure fashion?	Checked wallet and allowed to keep it.	Section 40.61(f)(2) states: "Allow the employee to keep his or her wallet."	None
7	Does the collector explain the basic collection procedure to the employee and show the employee the instructions on the back of the CCF?	Yes	Section 40.61(e) states: "Explain the basic collection procedure to the employee, including showing the employee the instructions on the back of the CCF."	None

#	Question	Finding	Regulation	Action Item
8	After the employee has removed any outer clothing and displayed the contents of their pockets, does the collector instruct the employee to wash and dry his/her hands?	Yes, however the collector did not watch the entire hand washing process and worked on filling out the CCF instead.	Section 40.63 states: "As the collector, you must take the following steps before the employee provides the urine specimen: (b) Instruct the employee to wash and dry his or her hands at this time. Tell the employee not to wash his or her hands again until after delivering the specimen to you. Do not give the employee any further access to water or other materials that could be used to adulterate or dilute a specimen."	While not in violation of the regulations it is best practices to monitor the employee at all times while in the testing process. Multi-tasking during this portion of the procedure is not ensuring that the employee is not accessing materials that could be used to adultrate the specimen.
9	Is there a source of water for hand washing, which, if practicable, is external to the privacy enclosure?	Yes	Section 40.41(e)(2) states: "Provide a source of water for washing hands that, if practicable, should be external to the closed room where urination occurs. If an external source is not available, this requirement may be met by securing all sources of water and other substances that could be used for adulteration and substitution (e.g., water faucets, soap dispensers) and providing moist towelettes outside the closed room."	None

#	Question	Finding	Regulation	Action Item
10	Are collection containers sealed, and does the employee or collector remove the sealed wrapper in the presence of the employee?	Yes	Appendix A states: "1. Collection Container ... (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." Section 40.63(c) states: "Select, or allow the employee to select, an individually wrapped or sealed collection container from collection kit materials. Either the collector or the employee, with both present, must unwrap or break the seal of the collection container. Do not unwrap or break the seal on any specimen bottle at this time. Do not allow the employee to take anything from the collection kit into the room used for urination except the collection container."	None
11	After the employee washes his/her hands, is the employee provided with a single-use plastic container from the collection kit which can hold at least 55 mL of urine? Does the collector assure that the employee takes nothing into the room used for urination except the collection container?	Yes	Part 40 Appendix A states: "The Collection Kit. (1)(a) Contents: Single-use container, made of plastic, large enough to easily catch and hold at least 55 mL of urine voided from the body." Section 40.63(c) states: "Do not allow the employee to take anything from the collection kit into the room used for urination except the collection container."	None

#	Question	Finding	Regulation	Action Item
12	Is the employee then required to remain in the presence of the collector (with no access to water, soap or other adulterating agents) until entering the privacy enclosure to provide the specimen?	Yes	Section 40.63(b) states: "Instruct the employee to wash and dry his or her hands at this time. Tell the employee not to wash his or her hands again until after delivering the specimen to you. Do not give the employee any further access to water or other materials that could be used to adulterate or dilute a specimen."	None

#	Question	Finding	Regulation	Action Item
13	Does the collector ensure that in the privacy enclosure for urination:(1) all sources of clear water have been eliminated, (2) possible specimen contaminants have been removed; and (3) all places where paraphernalia could be hidden were secured or removed?	The only places that might be used to hide paraphernalia were the toilet paper holder and a movable tray table that is currently in the room. The collector explained that they check the toilet paper holder after each collection and agreed that they would remove the small tray table to another location.	Section 40.43(b) states: "As a collector, you must do the following before each collection to deter tampering with specimens:(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 is blue; (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) Tape or otherwise secure shut any movable toilet tank top, or put bluing in the tank;(6) Ensure that undetected access (e.g., through a door not in your view) is not possible;(7) Secure areas and items (e.g., ledges, trash receptacles, paper towel holders, under-sink areas) that appear suitable for concealing contaminants; and (8) Recheck items in paragraphs (b)(1) through (7) of this section following each collection to ensure the site's continued integrity."	The collector must provide a signed statement certifying that she has read and fully understands the requirements of 49 CFR Part 40.43 (b). The collector will include as part of the statement an explanation of how they check the toilet paper holder after each collection and that they have removed the small table currently located in the collection room.

#	Question	Finding	Regulation	Action Item
14	If a non-dedicated facility (public restroom or hospital examining room) is used for collections, is the location used for testing secured during drug testing by: 1) visually inspecting the privacy enclosure; 2) assuring that undetected access (e.g., through a rear door) is prevented; and 3) posting limited access signs during the collection process?	N/A	Section 40.43(c) states: "If the collection site uses a facility normally used for other purposes, like a public rest room or hospital examining room, you must, as a collector, also ensure before the collection 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 distraction of the collector. Limited-access signs must be posted."	None
15	Does the water in the toilet contain a bluing agent? And is the toilet tank secured if it contains a feeder hose, or blued if it does not?	Yes	Section 40.43(b)(2) states: "Ensure that the water in the toilet is blue." Section 40.43(b)(5) states: "Tape or otherwise secure shut any movable toilet tank top, or put bluing in the tank."	None
16	UPON RECEIPT OF THE SPECIMEN, DID THE COLLECTOR CORRECTLY FOLLOW THE REQUIRED ACTIONS?			
17	Does the collector then observe that the specimen quantity is at least 45ml and check the split specimen box in Step 2?	Yes	Section 40.65(a) states: "Sufficiency of specimen. Check to ensure that the specimen contains at least 45 mL of urine." Section 40.71(b) states: "As a 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."	None

#	Question	Finding	Regulation	Action Item
18	Does the collector next: (1) determine the temperature of the specimen, using the temperature strip attached to the collection container within 4 minutes of receiving the specimen; and(2) mark the appropriate temperature box?	Yes, however the collector did not understand how to read the temp. tape color coding and determined that the specimen was in temp. when in reality the temp tape recorded that it was one degree below acceptable range. The collector did not understand that a color dot of tan means that temp of the specimen is one degree cooler than the temp above the dot.	Section 40.65(b) states: "Temperature. The collector must check the temperature of the specimen no later than four minutes after the employee has given the collector the specimen. (1) The acceptable temperature range is 32-38 deg. C / 90-100 deg. F.(2) The collector 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)."	The collector must provide a signed statement certifying that she has read and fully understands the requirements of 49 CFR Part 40.65(b). The collector should also include in the statement that they have read the article “Reading the Temperature Strip-Doing it Right” in the January 2015 FTA Drug and Alcohol Regulations Updates newsletter. This statement must also include an explanation from the DAPM of how this requirement will be met moving forward.
19	Are the two specimen bottles sealed until it is time to pour the sample from the collection container?	Yes	Section 40.63(c) states: "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."	None
20	After specimen collection and temperature reading, does the collector pour at least 30 mL of urine into the primary specimen bottle?	Yes	Section 40.71(b)(2) states: "The collector, 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."	None

#	Question	Finding	Regulation	Action Item
21	Does the collector pour at least 15 mL of the remaining urine specimen into the second specimen bottle to be used as the split specimen?	Yes	Section 40.71(b)(3) states: "The collector, 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."	None
22	WERE THE CUSTODY AND CONTROL FORM AND SPECIMEN BOTTLES PROPERLY COMPLETED AND SEALED?			
23	Does the employer utilize the standard five-part, carbonless, Federal Drug Testing Custody and Control Form?	Yes	Section 40.45(a) states: "The Federal Drug Testing Custody and Control Form (CCF) must be used to document every urine collection required by the DOT drug-testing program. The CCF must be a five-part carbonless manifold form. You may view this form on the Department's web site (http://www.dot.gov/ost/dapc) or the HHS web site (http://www.health.org/workplace/)."	None
24	Does the collector complete Step 1 of the custody and control form by selecting:(1) the reason for the test (e.g., pre-employment), and(2) the drug tests to be performed (e.g., THC, COC, PCP, OPI, AMP)?	Yes	Section 40.63(a) states: "The collector must complete Step 1 of the CCF before the employee provides the urine specimen."	None

#	Question	Finding	Regulation	Action Item
25	Does the collector securely place tamper-evident bottle seals over the bottle caps/lids and down the sides of each specimen bottle?	Yes	Section 40.71(b)(4) states: "You [the collector], not the employee, must place and secure (i.e., tighten or snap) the lids/caps on the bottles." Section 40.71(b)(5) states: "You [the collector], 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."	None
26	Does the collector write the date on each tamper-evident specimen bottle seal, only after the seals are affixed to the bottles?	Yes	Section 40.71(b)(5) states: "You [the collector], 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." Section 40.71(b)(6) states: "You [the collector], not the employee, must then write the date on the tamper-evident bottle seals."	None
27	Does the employee initial each tamper-evident specimen bottle seal only after the seals are affixed to the bottles and dated by the collector?	Yes	Section 40.71(b)(7) states: "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."	None

#	Question	Finding	Regulation	Action Item
28	After the tamper-evident specimen bottle seals are initialed by the employee, does the collector 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?	Yes, however review of Chillicothe Transit System records revealed that several of the completed CCFs had a blank in the evening phone number section. The collector at the mock test did ask to have me complete this section when I left it blank.	Section 40.73(a)(1) states: "The collector must do the following in the employee's presence to complete the collection. 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 print the employee's name in the appropriate place."	The collector must provide a signed statement certifying that she has read and fully understands the requirements of 49 CFR Part 40.73(a)(1). This statement must also include an explanation from the DAPM of how this requirement will be met moving forward in regards to ensuring that all collectors at the site remember to get the evening phone number section filled in.
29	After the employee completes (Copy 2) Step 5 of the CCF, and before completing Step 4 of the CCF, does the collector review the information entered on the CCF for accuracy and completeness?	Yes, see above	Section 40.73(a)(3) states: "As the collector, you must do the following things to complete the collection process Ensure that all copies of the CCF are legible and complete."	Yes, See above

#	Question	Finding	Regulation	Action Item
30	After the employee completes (Copy 2) Step 5 of the CCF, does the collector then complete Step 4 (i.e., providing a signature, printed name, date, time of collection, and name of delivery service)?	Yes	Section 40.73(a)(2) states: "Complete the chain of custody on the CCF (Step 5) 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." Section 40.45(b)(4) states: "As a collector, you may use a CCF with your name, address, telephone number, and fax number preprinted, but under no circumstances may you sign the form before the collection event."	None

#	Question	Finding	Regulation	Action Item
31	After completing Step 4 of the CCF, does the collector place the sealed specimen bottles and Copy 1 of the CCF in a leak proof plastic bag, with absorbent material, and then seal the bag?	Yes	Section 40.73(a) states: "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." Section 40.73(a)(5) states: "Place the specimen bottles and Copy 1 of the CCF in the appropriate pouches of the plastic bag." Appendix A states: "3. Leak-Resistant Plastic Bag. 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.. The sealing methodology must be such that once the compartments are sealed, any tampering or attempts to open either compartment will be evident." Appendix A states: "4. Absorbent material. 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." Section 40.73(a)(6) states: "Secure both pouches of the plastic bag."	None

#	Question	Finding	Regulation	Action Item
32	Are copies 1 through 5 of the custody and control form sent to the correct individuals:(Copy 1) Laboratory, (Copy 2) MRO, (Copy 3) Collector, (Copy 4) DER, and (Copy 5) Employee?	Yes	Section 40.73(a) states: "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." Section 40.73(a)(4) states: "Remove Copy 5 of the CCF and give it to the employee." Section 40.73(a)(9) states: "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."	none
33	To the greatest extent possible, does the collector keep the employee's collection container within his/her and the employees view between the time the employee has urinated and the specimen bottle is sealed?	Yes	Section 40.43(d)(2) states: "To the greatest extent possible, the collector should keep the employee's collection container within his/her and the employees view between the time the employee has urinated and the specimen is sealed."	None

#	Question	Finding	Regulation	Action Item
34	Does the collector have only one employee under his/her supervision at one time until the collection process is completed (i.e., specimen has been collected, the urine specimen bottle has been sealed and initialed, the custody and control form has been completed and the employee has departed)?	Yes	Section 40.43(d) states: "As a collector, you must take the following additional steps to ensure security during the collection process:(1) To avoid distraction that could compromise security, you are limited to conducting a collection for only one employee at a time. However, during the time one employee is in the period for drinking fluids in a "shy bladder" situation (see Section 40.193(b)), you may conduct a collection for another employee."	None
35	WERE THE INFORMATION BLOCKS COMPLETED CORRECTLY BY THE COLLECTOR AND LEGIBLE ON ALL PARTS OF THE STANDARD FIVE PART DRUG TESTING CUSTODY AND CONTROL FORM?			

#	Question	Finding	Regulation	Action Item
36	Were the following items completed and legible on the custody and control form:(1) employee ID No. or SSN;(2) employers name, address, telephone and fax numbers; and(3) MROs name, address, telephone and fax numbers (C/TPA contact information may also be included, but is not required)?	See #28 above in regards to the evening phone number section	Section 40.63(a) states: "As the collector, you must take the following steps before the employee provides the urine specimen: (a) Complete Step 1 of the CCF." Section 40.73(a)(3) states: "Ensure that all copies of the CCF are legible and complete." Section 40.45(b)(2) states: "The CCF must include the names, addresses, telephone numbers and fax numbers of the employer and the MRO, which may be preprinted, typed, or handwritten. The MRO information must include the specific physician's name and address, as opposed to only a generic clinic, health care organization, or company name. This information is required, and it is prohibited for an employer, collector, service agent or any other party to omit it. In addition, a C/TPA's name, address, fax number, and telephone number may be included, but is not required."	See # 28 above
37	Is the information entered in Step 4 of the CCF complete and legible and contain the following:(1) Collector signature and printed name;(2) Time of collection;(3) Date of collection; and(4) Name of delivery service transferring specimen to lab?	Yes	Section 40.73(a)(2) states: "Complete the chain of custody on the CCF (Step 5) 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."	None

#	Question	Finding	Regulation	Action Item
38	DOES THE SPECIMEN COLLECTION SITE HAVE THE REQUIRED SECURITY FEATURES?			
39	Is security of collection materials and completed specimens maintained at all times, and are only authorized personnel permitted in areas where specimens are collected or stored?	Yes	Section 40.43(e) states: "If operating a collection site, the collector must implement policy and procedures to prevent unauthorized personnel from entering any part of the site in which urine specimens are collected or stored."	None

#	Question	Finding	Regulation	Action Item
40	How often is the security of the designated privacy enclosure used for urine collections checked?	Before and after each collection	Section 40.43(b)(8) states: "Recheck items in paragraphs (b)(1) through (7) of this section following each collection to ensure the site's continued integrity." Section 40.43(b) states: "As a collector, you must do the following before each collection to deter tampering with specimens:(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 is blue;(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) Tape or otherwise secure shut any movable toilet tank top, or put bluing in the tank;(6) Ensure that undetected access (e.g., through a door not in your view) is not possible;(7) Secure areas and items (e.g., ledges, trash receptacles, paper towel holders, under-sink areas) that appear suitable for concealing contaminants ..."	None

#	Question	Finding	Regulation	Action Item
0	THIS COMPLETES THE REVIEW OF A NORMAL URINE COLLECTION. NOW I WOULD LIKE TO ASK YOU SOME QUESTIONS ABOUT YOUR PROCEDURES AND REFERENCE MATERIALS			
41	ARE THE PROPER PROCEDURES USED WHEN THERE ARE PROBLEMS DURING THE COLLECTION?			
42	Do you have:(1) a current copy of 49 CFR Part 40, and (2) the current "DOT Urine Specimen Collection Guidelines?"	Yes, printed and on the computer	Section 40.33(a) states: "Basic information. You must be knowledgeable about this part, the current "DOT Urine Specimen Collection Procedures Guidelines," and DOT agency regulations applicable to the employers for whom you perform collections, and you must keep current on any changes to these materials. The DOT Urine Specimen Collection Procedures Guidelines document is available from ODAPC (Department of Transportation, 400 7th Street, SW., Room 10403, Washington DC, 20590, 202-366-3784, or on the ODAPC web site (http://www.dot.gov/ost/dapc)."	None

#	Question	Finding	Regulation	Action Item
43	What is done if the employee does not have a photo ID?	They would contact the DER for positive identification of the employee	Section 40.61(c) states: "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."	None
44	Is identification of the employee by another employee being tested accepted?	No, they would contact the DER	Section 40.61(c) states: "... 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."	None

#	Question	Finding	Regulation	Action Item
45	What actions must the collection site take if an employee does not arrive to take a scheduled test?	Currently employees arrive with no advanced notification. If they had advanced notification they would contact the DER if the employee had not shown up in the time frame required.	Section 40.241(a) states: "The collector must take the following steps before actually beginning a collection: 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, notify the DER that the employee has not reported for testing. This is a refusal to take a DOT drug test."	None
46	What is done if an employee says he/she is not ready to proceed with the urine collection process because an employee representative is delayed in arriving?	Explain that they must begin the test immediately, or it will be considered a refusal to test, record it in notes and contact DER	Section 40.61(b) states: "[The collector must] 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."	None

#	Question	Finding	Regulation	Action Item
47	What is done if an employee says he/she is not ready to begin the urine collection process because of inability to urinate at the time?	Same as above, and begin shy bladder procedures if required.	Section 40.61(b) states: "[The collector must] 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."	None
48	What is done if you find the employee has material that appears to have been brought with the intent to alter or substitute the specimen?	Explain the concern to the employee, and explain and begin an observed collection	Section 40.61(f)(5) states: "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 Section 40.67)."	None

#	Question	Finding	Regulation	Action Item
49	If an employee is clearly and unequivocally attempting to adulterate or substitute their urine specimen, what steps are taken by the collector?	Begin a direct observaton collection and record reason in remarks section of CCF.	Section 40.63(e) states: "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 Section 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."	None
50	What is done if the employee admits to adulterating or substituting the specimen?	Create and sign a statement of what they heard and report a refusal to test.	Section 40.159(c) states: "If the employee admits to having adulterated or substituted the specimen, you must, on the same day, write and sign your own statement of what the employee told you. You must then report a refusal to test in accordance with Section 40.163."	None

#	Question	Finding	Regulation	Action Item
51	If an employee refuses to cooperate with the collection process, what three steps are taken by the collector?	They would stop the process. Document the refusal in the remarks section of the CCF and sign and date it. Notify DER immediately of the refusal to test.	Section 40.191(d) states: "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 employees 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 refusal in the "Remarks" line (Step 2), and sign and date the CCF."	None

#	Question	Finding	Regulation	Action Item
52	What would you do if the specimen is out of the acceptable temperature range, or appears to be adulterated or substituted?	Mark the temperature as not in range or document the suspected adulteration. Finish the initial collection including packaging. Begin a second collection under direct observation.	Section 40.65(b)(1) states: "(1) The acceptable temperature range is 32-38 deg. C /90-100 deg. F." Section 40.65(b)(4) states: "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." Section 40.65(b)(5) states: "If the specimen temperature is outside the acceptable range, you must immediately conduct a new collection using direct observation procedures (see Section 40.67)."	None
53	If an initial specimen is tampered with or out of the acceptable temperature range, and a second specimen is collected under direct observation, which specimens are sent to the lab?	Both	Section 40.65(b)(6) states: "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."	None

#	Question	Finding	Regulation	Action Item
54	If an employee provides an adulterated or out-of-temperature sample, and refuses to allow a second specimen to be collected under observed collection, what is done with the initial sample?	Discarded following proper disposal methods.	Section 40.65(b)(7) states: "In a case where the employee refuses to provide another specimen (see Section 40.191(a)(3)) or refuses to provide another specimen under direct observation (see Section 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."	None
55	If you as the collector must complete an observed collection, is it required that you must record the reason for the observed collection, and if so, how?	Yes, marking it as an observed collection on the new CCF and putting the reason why in the remarks section.	Section 40.67(e) states: "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 Section 40.67(b)) in the "Remarks" line (Step 2)."	None
56	Does this collection site always have available a same-gender collector, in case an observed collection is needed?	Yes	Section 40.67(g) states: "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."	None

#	Question	Finding	Regulation	Action Item
57	Can you describe the procedures for conducting a directly-observed test?	Yes	Section 40.67(i),(j),(k) state: "(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."	None
59	What is done if the employee possesses a prosthetic or other device used to tamper with the collection?	Record the information in the remarks section of the CCF and document the incident with a signed statement. Report the refusal to test to the DER	Section 40.191(a) states: (a) As an employee, you have refused to take a drug test if you: (10) Possess or wear a prosthetic or other device that could be used to interfere with the collection process.	None
59	ARE THE PROPER AND COMPLETE SHY BLADDER PROCEDURES IN PLACE?			

#	Question	Finding	Regulation	Action Item
60	If the employee is unable to provide a specimen of at least 45 milliliters, what is done?	Begin shy bladder process. Which they explained each step of and they have a process for completing with the employee. They will be purchasing a measuring cup for the use of providing the 45 milliliters for the employee in a standard way.	Section 40.193(b) states: "As the collector, you must do the following: (2) 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."	None
61	What is done with the original insufficient specimen?	Discard it using approved disposal methods.	Section 40.193(b) states: "As the collector, you must do the following: (1) Discard the insufficient specimen, except where the insufficient specimen was out of temperature range or showed evidence of adulteration or tampering (see Section 40.65(b) and (c))."	None
62	What is done if the employee refuses to attempt to provide a new specimen, or leaves the collection site before the process is complete?	Record it as a refusal to test in the remarks section. Sign and date the form and notify DER immediately.	Section 40.193(b)(3) states: "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 the fact on the "Remarks" line of the CCF (Step 2), and immediately notify the DER. This is a refusal to test."	None

#	Question	Finding	Regulation	Action Item
63	What is done if the employee has not provided a sufficient specimen within three hours of the first unsuccessful attempt to provide the specimen?		Section 40.193(b) states: "As the collector, you must do the following: (1) Discard the insufficient specimen, except where the insufficient specimen was out of temperature range or showed evidence of adulteration or tampering (see Section 40.65(b) and (c))."	
64	What is done if it is time to close the collection facility and the employee is still in the "shy bladder" process?	They would stay until the three hour time limit is up or the employee has provided the full specimen.	Section 40.193(b)(2) states: "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." The employee must be afforded the right to a three hour waiting period to provide a specimen. Closing the collection site before the three hour period is complete is a violation of the employees rights under Section 40.193(b)(2).	None

#	Question	Finding	Regulation	Action Item
65	If an event occurs during the urine collection process which prevents the completion of a valid test or collection (e.g., a procedural or paperwork error), what is done by the collector, and can another collection be performed as part of this effort?	They would correct the mistake if possible, and would contact the DER to have the employee come back for another test immediately if the mistake is not correctable.	Section 40.205(a) states: "The collector has the responsibility of trying to successfully complete a collection procedure for each employee. (1) If, during or shortly after the collection process, any event that prevents the completion of a valid test or collection (e. g. , a procedural or paperwork error) becomes evident, the collector must try to correct the problem promptly, if doing so is practicable. Another collection may be conducted as part of this effort.(2) 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."	None
66	DOES THE COLLECTOR HAVE AN UNDERSTANDING OF ERRORS THAT MAY CAUSE A TEST TO BE CANCELLED, AND METHODS FOR ITS CORRECTION?			
67	What is the impact on a test result if the collector does not sign AND print his/her name in Step 4 (certification statement) of the CCF, so that the portion of the CCF is blank?	Yes, they listed the fatal flaws and also gave examples of how to correct non-fatal flaws.	Section 40.199(b) states: "The following are "fatal flaws": (1) There is no printed collector's name and no collector's signature."	None

#	Question	Finding	Regulation	Action Item
68	What is the impact on a test result if the collector uses a non-DOT drug testing form for a DOT-required test, and the problem is not corrected?	They understand that the test would be cancelled.	Section 40.203(d) states: "The following are correctable flaws that you must attempt to correct:(3) The collector uses a non-Federal form or an expired Federal form for the test. This flaw may be corrected through the procedure set forth in Section 40.205(b)(2) of this part, provided that the collection testing process has been conducted in accordance with the procedures of this part in an HHS-certified laboratory... . Beginning November 1, 2001, if the problem(s) is not corrected, the test must be cancelled."	none

#	Question	Finding	Regulation	Action Item
69	What is the impact on a test result if the employee doesn't sign the certification statement on Copy 2 (Step 5) of the CCF and the collector doesn't make note of this on the "Remarks" line?	They understand that if they have not noted it as a refusal to sign by the employee in the remarks section then the test could be cancelled.	Section 40.203(c) states: "As the MRO, when you discover a "correctable flaw" during your review of the CCF, you must cancel the test unless the flaw is corrected." Section 40.203(d) states: "The following are correctable flaws that you [the MRO] must attempt to correct: (1) The employee's signature is omitted from the certification statement, unless the employee's failure or refusal to sign is noted on the "Remarks" line of the CCF." Section 40.205(b) states: "If, as a collector, laboratory, MRO, employer, or other person implementing these drug testing regulations, you become aware of a problem that can be corrected (see Section 40.203), but which has not already been corrected under paragraph (a) of this section, you must take all practicable action to correct the problem so that the test is not cancelled."	None

#	Question	Finding	Regulation	Action Item
70	What is the impact on a test result if the collector doesn't sign the certification statement (Step 4) of the CCF?	If a correction is not completed and the CCF signed then the test could be cancelled	Section 40.203 states: "The following is a "correctable flaw" that laboratories must attempt to correct: The collector's signature is omitted on the certification statement on the CCF." Section 40.205(b) states: "If, as a collector, laboratory, MRO, employer, or other person implementing these drug testing regulations, you become aware of a problem that can be corrected (see Section 40.203), but which has not already been corrected under paragraph (a) of this section, you must take all practicable action to correct the problem so that the test is not cancelled." Section 40.205(c) states: "If the correction does not take place, as the MRO you must cancel the test."	None
0	THIS COMPLETES THE REVIEW OF COLLECTOR QUESTIONS. -- FILL OUT THE CHECKLIST TO THIS POINT. THEN, CONTINUE WITH THE COLLECTION SITE SUPERVISOR TO REVIEW THE FOLLOWING QUESTIONS.			
71	DID THE SUPERVISOR ANSWER ALL QUESTIONS CORRECTLY?			

#	Question	Finding	Regulation	Action Item
72	How often does the collection site ship specimens to the laboratory?	Daily at 3:30pm	Section 40.73(b) states: "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."	None
73	How soon after a collection are the CCF copies sent to the MRO and DER?	At the close of business day each day	Section 40.73(a)(9) states: "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..."	None
74	How long must the collection site retain the Collectors copy (Copy 3) of the CCF?	For at least 1 year	Section 40.73(a)(9) states: "... Keep Copy 3 for at least 30 days, unless otherwise specified by applicable DOT agency regulations."	None

#	Question	Finding	Regulation	Action Item
75	Have each of the urine collectors hired since August 1, 2001 received training in accordance with the amended Part 40 regulations (effective August 9, 2001)? If so, could I see their training records?	Yes, showed certs.	Section 40.33(d) states: "Schedule for qualification training and initial proficiency demonstration. The following is the schedule for qualification training and the initial proficiency demonstration you must meet:(3) If you become a collector on or after August 1, 2001, you must meet the requirements of paragraphs (b) and (c) of this section before you begin to perform collector functions." Section 40.33(b) states: "Qualification training. You must receive qualification training meeting the requirements of this paragraph. Qualification training must provide instruction on the following subjects:(1) All steps necessary to complete a collection correctly and the proper completion and transmission of the CCF;(2) "Problem" collections (e.g., situations like "shy bladder" and attempts to tamper with a specimen);(3) Fatal flaws, correctable flaws, and how to correct problems in collections; and(4) The collector's 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." Section 40.33(c) states: "Initial Proficiency Demonstration. Following your	None

#	Question	Finding	Regulation	Action Item
			completion of qualification training under paragraph (b) of this section, you must demonstrate proficiency in collections under this part by completing five consecutive error-free mock collections." Section 40.33(g) states: (g) Documentation. You must maintain documentation showing that you currently meet all requirements of this section. You must provide this documentation on request to DOT agency representatives and to employers and C/TPAs who are using or negotiating to use your services."	
76	If a drug test is cancelled because of a collector mistake, what corrective action is taken with the collector who made the mistake?	If a test is cancelled because of a collection error that collector receives corrective action training that is documented and put in the collectors file.	Section 40.33(f) states: "Error Correction Training. If a mistake is made in the collection process that causes a test to be cancelled (i.e., a fatal or uncorrected flaw), error correction training must be done. This training must occur within 30 days of the date notified of the error that led to the need for retraining."	None
77	Once a collector has been notified that they must receive error correction training, within how many days must the collector receive error-correction training?	30 days	Section 40.33(f) states: "Error Correction Training. If a mistake is made in the collection process that causes a test to be cancelled (i. e. , a fatal or uncorrected flaw), error correction training must be done. This training must occur within 30 days of the date notified of the error that led to the need for retraining."	None

#	Question	Finding	Regulation	Action Item
78	Once a collector has been notified that a correctable flaw has occurred, how many days does the collector have to supply information correcting the flaw?	Within the same business day as the notification of the error.	Section 40.205(b)(1) and (2) both state: "You must supply this information on the same business day on which you are notified of the problem, transmitting it by fax or courier."	None

#	Question	Finding	Regulation	Action Item
79	When a flaw is identified after a drug test is completed, what is the process by which the error is corrected?		Section 40.205(b)(1) states: "If the problem resulted from the omission of required information, the person responsible for providing that information must supply in writing the missing information and a statement that it is true and accurate. For example, suppose a collector forgot to make a notation on the "Remarks" line of the CCF that the employee did not sign the certification. When the problem is called to your attention, a signed statement that the employee failed or refused to sign the certification and that your statement is true and accurate must be supplied. The collector must supply this information on the same business day when notified of the problem, transmitting it by fax or courier." Section 40.205(b)(2) states: "If the problem is the use of a non-Federal form, the person responsible for the use of the incorrect form must provide a signed statement that the incorrect form contains all the information needed for a valid DOT drug test, that the incorrect form was used inadvertently or as the only means of conducting a test, in circumstances beyond your control. The statement must also list the steps taken to prevent future use of non-Federal forms for DOT tests. For this flaw to have been corrected, the test of the specimen must have	

#	Question	Finding	Regulation	Action Item
			occurred at a HHS-certified laboratory where it was tested using the testing protocol in this part. This information must be supplied on the same business day when notified of the problem, transmitting it by fax or courier." Section 40.205(b)(3) states: "Maintain the written documentation of a correction with the CCF." Section 40.205(b)(4) states: "Mark the CCF in such a way (e.g., stamp noting correction) as to make it obvious on the face of the CCF the flaw is corrected."	

#	Question	Finding	Regulation	Action Item
80	Was the Urine Collection Site prepared for the audit team, and did the vendor cooperate with the audit team and facilitate the audit process, including producing the required records?	Yes	Section 40.331(c) states: "If you are a service agent, you must, upon request of DOT agency representatives, provide the following:(1) Access to your facilities used for this part and DOT agency drug and alcohol program functions.(2) All written, printed, and computer-based drug and alcohol program records and reports (including copies of name-specific records or reports), files, materials, data, documents/documentation, agreements, contracts, policies, and statements that are required by this part and DOT agency regulations. You must provide this information at your principal place of business in the time required by the DOT agency.(3) All items in paragraph (b)(2) of this section must be easily accessible, legible, and provided in an organized manner. If electronic records do not meet these standards, they must be converted to printed documentation that meets these standards."	None
0	THIS COMPLETES THE URINE COLLECTION QUESTIONNAIRE. THANK YOU FOR YOUR TIME AND ASSISTANCE.			