Department of Health and Human Services
Substance Abuse and Mental Health Services Administration
Center for Substance Abuse Prevention

Urine Specimen Collection Handbook

for

Federal Agency Workplace Drug Testing Programs

November 1, 2004
(Effective Date)

This handbook provides additional guidance to supplement the urine specimen collection requirements contained in the Mandatory Guidelines for Federal Workplace Drug Testing Programs that were published in the Federal Register on April 13, 2004 (69 FR 19644), with a November 1, 2004, implementation date.

Note: This handbook does <u>not</u> apply to specimens collected under the Department of Transportation Procedures for Transportation Workplace Drug and Alcohol Testing Programs (49 CFR Part 40).

Previous Versions of this Handbook are Obsolete

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Chapter 1. The Collector

A collector is a trained individual who instructs and assists a donor at a collection site, and receives the specimen provided by a donor.

The following restrictions apply:

- The immediate supervisor of an employee may not serve as the collector when that employee is tested, unless there is no feasible alternative;
- A co-worker who is in the same testing pool or who works with an employee on a daily basis may not serve as a collector when that employee is tested, unless there is no feasible alternative;
- An individual working for an HHS-certified laboratory may not serve as a collector if that individual can link the donor with the specimen drug test result or laboratory report;
- An individual who has a personal relationship with the employee (e.g., spouse, ex-spouse, relative, close personal friend) may not serve as the collector, unless there is no feasible alternative.

To qualify as a collector for a Federal agency program, an individual must:

- Read and understand the HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs,
- Read and understand any guidance provided by the Federal agency which is consistent with HHS Mandatory Guidelines, and
- Successfully complete training to perform collections in accordance with the procedures in this manual.

The collector should have identification with his/her name and his/her employer's name, address, and telephone number. The collector is required to provide his or her identification (or collection company identification) if requested by the donor. There is no requirement for the collector to have a photo ID or to provide his or her driver's license with an address. Also, the collector is not required to provide any certification or other documentation to the donor proving the collector's training in the collection process.

The collector must have the name and telephone number of the Federal agency's designated representative to contact in the event that any problems or issues arise during the collection.

Chapter 2. Collector/Collection Site Records

Collector training records must be maintained for a minimum of two years to document a collector's qualifications for collecting Federal agency specimens. The collector should maintain

the original training documentation, and provide copies for his/her employer and the Federal agency. Other collection site records must be stored for a minimum of two years. This includes the collector copy (Copy 3) of the Federal Drug Testing Custody and Control Form (Federal CCF) for each specimen. Collection records must be stored and disposed of in a manner that ensures donor confidentiality is maintained.

Chapter 3. Collection Site Security

The collection site must be secure to prevent unauthorized access to specimens, collection supplies, and collection site records. A permanent site that is used solely for specimen collections must be secured at all times. At facilities that are not dedicated specimen collection sites, the area of the site used for specimen collections must be secured during the time a specimen is collected.

Chapter 4. Blind Quality Control Samples

Each Federal agency is required to have blind quality control (QC) samples (i.e., negative samples, drug positive samples, adulterated samples, substituted samples) submitted along with the donor specimens. The blind samples may be purchased by the Federal agency and supplied to the collector, or purchased by the collector and submitted to a laboratory with an agency's specimens. The Mandatory Guidelines specify the number of blind QC samples a Federal agency must submit based on the ratio of QC samples to donor specimens and specify the approximate percentage of each type (i.e., 75% negative, 15% positive for one or more drugs, 10% either adulterated or substituted).

Each blind QC sample is submitted with a Federal CCF completed as for a donor specimen, with the following exceptions:

- Because there is no donor, the collector completes the donor's section of the CCF and writes fictitious initials on the specimen bottle label/seal.
- The collector indicates that the sample is a 'blind QC sample' on the Medical Review Officer (MRO) copy where the donor would normally provide a signature (Step 5 on Copy 2 of the CCF).
- The collector may either discard Copy 5 of the CCF (the donor copy) or maintain it with Copy 3 of the CCF (the collector copy).

If the collector purchases the samples for the Federal agency's blind QC program, the collector must send the supplier's information to the MRO (e.g., the content and concentration of the blind samples) to enable the MRO to interpret the results and report them to the agency.

Chapter 5. The Federal Drug Testing Custody and Control Form

Federal agencies are required to use the Office of Management and Budget (OMB) approved

Federal CCF when collecting urine specimens for their workplace drug testing programs.

The following employers are prohibited from using the Federal CCF:

- Private-sector companies,
- States,
- Department of Justice programs, and
- Non-DOT testing conducted by DOT-regulated employers.

In the rare instances when the collector, either by mistake or as the only means to conduct a collection under unusual circumstances (e.g., post-accident test with insufficient time to obtain the Federal CCF), uses a non-Federal form for a Federal agency collection:

- The use of a non-Federal form does not, in and of itself, constitute a reason for the laboratory to reject the specimen for testing or for the MRO to cancel the test.
- The collector must send a signed statement with the specimen stating the reason why the Federal CCF was not used for the Federal agency collection.
- If a laboratory or MRO discovers the use of a non-Federal form, the collector will be notified to provide a memorandum explaining the use of the incorrect form.

All urine specimens must be collected using chain of custody. Chain of custody is the term used to describe the process of documenting the handling and storage of a specimen from the time a donor gives the specimen to the collector to the final disposition of the specimen. For specimens collected under the Mandatory Guidelines, the collector begins the chain of custody documentation at the collection site using the Federal CCF.

Federal CCFs are available from a number of companies that print various types of forms. A list of suppliers and a sample of the Federal CCF (OMB No. 0930-0158) are on the SAMHSA website **(http://workplace.samhsa.gov)**.

A. Federal CCF Description

The Federal CCF consists of the following five pages:

Copy 1 - Laboratory Copy
Copy 2 - MRO Copy
Copy 3 - Collector Copy
Copy 4 - Employer Copy
Copy 5 - Donor Copy

At the top of the Federal CCF, the laboratory must be identified by one of the following:

- A specific laboratory name and address,
- A list of addresses with check boxes to allow the collector to check the box for the laboratory to which the specimen will be delivered, or
- A corporate name and telephone number (the laboratory in the corporation that receives the specimen for testing prints its specific address when accessioning the specimen).

The bottom area of Copy 1 is reserved for the tamper-evident specimen bottle seal(s)/label(s). There must be:

- Two labels (i.e., one marked with the letter "A" to designate the primary specimen and the other marked with the letter "B" to designate the split specimen) to accommodate collecting split specimens, and
- Each label must have:
    - The same preprinted specimen identification number that appears at the top of the Federal CCF,
    - A place for the collector to annotate the date of the collection,
    - A place for the donor to initial each label after it is placed on the specimen bottle, and
    - If a single specimen collection procedure is used, the second label (i.e., the "B" label) is discarded by the collector.

B. Federal CCF Instructions for Use

Step 1. To be completed by the collector or Federal agency representative prior to the donor providing a specimen:

- The employer and MRO information may be preprinted or handwritten,
- The collector enters the donor's social security number (SSN) or employee I.D. number after verifying the donor's identity,
- The appropriate box is marked to indicate the reason for the test,
- The appropriate box is marked for the drug tests to be performed, and
- The collection site information may be preprinted or handwritten.

Step 2. To be completed by the collector after receiving the specimen from the donor and measuring the temperature of the specimen. This step requires the collector to mark the appropriate boxes to indicate that:

- The temperature of the specimen was or was not within the required temperature range,
- The collection was a split specimen or single specimen collection,
- No specimen was collected and why (if applicable), and
- A direct observed collection was performed and why (if applicable).

Step 3. To be performed by the collector. This step instructs the collector to:

- Seal the specimen container(s) (i.e., bottle, primary specimen bag, shipping bag),
- Date the seal(s),
- Have the donor initial the bottle seal(s) after placing the seal(s) on the bottle(s), and
- Have the donor complete step 5 on the MRO copy (Copy 2).

Step 5 (Copy 2). To be completed by the donor. The collector instructs the donor to:

- Read the certification statement.
- Print the following:
    - His or her name,
    - Date of collection,
    - Daytime and evening telephone numbers, and
    - Date of birth.
- Sign the certification statement.

Step 4. To be initiated by the collector and completed at the laboratory. The collector is required to:

- Sign the form to certify that the specimen was collected, labeled, sealed, and released for shipment to the laboratory in accordance with Federal requirements.
- Print his or her name.
- Record the following:
    - Time of the collection.
    - The date of collection.

- The specific name of the delivery service to which the specimen is released for shipment to the laboratory.
    - There is no requirement for couriers, express carriers, or postal service personnel to document chain of custody for the specimens during transit because they do not have access to the specimen bottle(s) or the Federal CCF.
- Do not make entries below the bold line in Step 4, entries in this area are made at the laboratory.

Step 5(a). To be completed by a certifying scientist to record the test result for the primary specimen.

Step 5(b). To be completed by a certifying scientist to record the test result for a split (Bottle B) specimen or for an aliquot of a single specimen tested at a second HHS-certified laboratory, with the name and address of the testing laboratory.

Step 6 (Copy 2). To be completed by the MRO to record the test result for a primary specimen.

Step 7 (Copy 2). To be completed by the MRO to record the test result for a split (Bottle B) specimen or second laboratory test result for a single specimen.

Chapter 6. Verification of Donor Identity

The donor must provide appropriate identification to the collector upon arrival at the collection site.

Acceptable forms of identification are:

- A photo identification (e.g., driver's license, employee badge issued by the employer, any other picture identification issued by a Federal, state, or local government agency),
- Identification by a Federal agency representative, or
- Other identification allowed under a Federal agency's workplace drug testing plan.

Unacceptable forms of identification are:

- Identification by a co-worker,
- Identification by another donor,
- Use of a single non-photo identification card (e.g., social security card, credit card, union or other membership cards, pay vouchers, voter registration card), or

- A faxed copy or photocopy of an identification document.

When the donor cannot meet the acceptable identification criteria listed above, the collector requests the donor to provide two items of identification bearing his or her signature:

1. If the donor can provide the two items, the collector will compare the signatures on the items to the donor's signature on the donor certification statement of the Federal CCF (Step 5).

   - If the signatures match, the collector must:

     o List on the "Remarks" line the two items of identification used to identify the donor,

     o Write "signature identification was confirmed," and

     o Continue with the collection process.

   - If the signatures do not match, the collector must:

     o Record on the "Remarks" line that "signature identification is unconfirmed,"

     o Discontinue the collection, and

     o Notify the Federal agency's designated representative.

2. If the donor does not have two items of identification with his or her signature, the collector must proceed with the collection and record sufficient information on the "Remarks" line of the Federal CCF to help the MRO and the agency make a determination regarding the validity of the specimen and the collection process. **Note:** *This is not considered a refusal to test.*

Chapter 7. Urine Specimen Collection

A. The Collection Site

A collection site is a permanent or temporary facility selected by the Federal agency where a donor provides a urine specimen for a drug test. The site must have all necessary personnel, supplies, equipment, facilities, and supervision to provide for specimen collection, security, and temporary storage, and have arrangements for the transfer of the specimens to a certified laboratory.

A urine specimen collection site must:

1. Provide for donor privacy while he or she provides the urine specimen. An observed collection must only be performed when required (see Chapter 7, Section D). The following facilities provide adequate privacy for urine collections:

   - A single-toilet restroom with a full-length door,

- A multi-stall restroom with partial-length doors, or
- A mobile restroom (e.g., a vehicle with an enclosed toilet stall).

2. Provide a source of water for washing hands:
   - If practical, the water source should be external to the restroom where urination occurs.
   - If the only source of water available is inside the restroom, the collector must:
     - Secure the water source before the collection (i.e., after the donor washes his or her hands), and
     - Restore the water source to allow the donor to wash his or her hands after the collection.
   - If a water source is not available, providing moist towelettes outside the restroom is an acceptable alternative.
3. Have a suitable clean surface for the collector to use as a work area. The collector work area may be located:
   - Outside the restroom, or
   - Inside the restroom only if the donor can have privacy while providing the urine specimen.
4. Have procedures or restrictions to prevent:
   - Unauthorized access to the site during the collection,
   - Unauthorized access to the collection materials/supplies,
   - Donor access to items that could be used to adulterate or dilute the specimen (e.g., soap, disinfectants, cleaning agents, water),
   - Unauthorized access to the specimen after it is collected, and
   - Unauthorized access to collection site records.
5. The collector must maintain line-of-sight custody or provide for the secure storage of specimens from the time the specimen is collected until it is sealed in a shipping container prior to transfer to an express carrier or courier for shipment to a laboratory.

B. Collection Supplies

The following items must be available at the collection site to conduct proper urine collections:

1. **Single-use plastic collection containers**. Each collection container must be:

   - Supplied as an individually sealed item using a tamper-evident system (e.g., in a sealed plastic bag, shrink wrapped, or another easily visible tamper-evident system),
   - Large enough to easily catch and hold at least 55 mL urine, and
   - Graduated with volume markings clearly showing the volume (e.g., 30 mL, 45 mL).

2. **Single-use plastic specimen bottles**. Each specimen bottle with cap must be:

   - Sealed using a tamper-evident system (e.g., sealed plastic bag, shrink wrap, or another easily visible tamper-evident system),
   - Able to hold at least 35 mL,
     - The split specimen bottle may be the same size or smaller than the primary specimen bottle, but able to hold at least 20 mL.
   - Leak-resistant (i.e., have screw-on or snap-on caps that prevent leakage),
   - Marked clearly to indicate the minimum levels of urine to be poured into each bottle (30 mL for the primary specimen and 15 mL for the split specimen), and
   - Designed so that the required tamper-evident bottle label/seal from the Federal CCF is not damaged when the donor initials it and has no overlap that conceals printed information.

3. **Temperature strips.** The temperature strips must be capable of temperature readings between 90°-100°F (32°-38°C). The temperature strips may be:

   - Affixed to the collection container as supplied, or
   - Affixed to the collection container after the donor gives the collection container with the specimen to the collector.

4. **Federal CCFs.** The standardized OMB-approved Federal CCFs as described in Chapter 5.

5. **Tamper-evident seals**. The Federal CCF has two tamper-evident labels/seals that are used to seal a single specimen bottle or two split specimen bottles. Occasionally, a tamper-evident label/seal provided with the Federal CCF will not properly adhere to the specimen bottle (e.g., due to moisture, temperature, or specimen bottle material). If this occurs, see Chapter 7, Section C, Step 18 for instructions on using the additional tamper-evident labels/seals.

6. **Leak-resistant plastic bags**. The plastic bag must have two sealable compartments or

pouches (i.e., one large enough to hold two specimen bottles and the other large enough to hold Copy 1 of the Federal CCF).

7. **Absorbent material**. The absorbent material is placed with the specimen bottles inside the leak-resistant plastic bag in case a specimen bottle leaks during shipment. The U.S. Postal Service and other express carriers require the use of absorbent material when shipping biological materials.

8. **Shipping containers**. Boxes or bags used to transport specimens to a laboratory must be securely sealed to prevent the possibility of undetected tampering. It is not necessary to use a shipping container/mailer if a courier hand delivers the sealed leak-resistant plastic bags containing the specimen bottles directly from the collection site to the laboratory.

9. **Bluing agent**. Bluing agent is added to the toilet bowl and water tank to prevent undetected specimen dilution by the donor.

10. **Secure temporary location**. It is the collector's responsibility to prevent unauthorized access to the specimen bottles and Federal CCF. Prior to placement in a shipping container, the sealed leak-resistant plastic bag containing the specimen bottle(s) and completed Copy 1 of the Federal CCF must be kept:

    - Within the collector's line-of-sight, or
    - In a secure temporary location (e.g., locked in a refrigerator or cabinet).

11. **Disposable gloves.** HHS recommends that collectors use single-use disposable gloves while handling specimens. The Occupational Safety and Health Administration has specific guidelines addressing protection of employees who are exposed to potentially infectious body fluids (29 CFR Part 1910.1030).

C. Collection Procedure (Single Specimen or Split Specimen)

1. Prepare the collection site to collect urine specimens (see "Collection Site" above):

    - Assemble supplies,
    - Turn off the water supply or secure water sources,
    - Ensure that there is bluing agent in the toilet,
    - Remove any soap, cleanser, disinfectant, or other potential adulterants, and
    - Inspect and/or secure areas or items that could be used to conceal adulterants (e.g., false ceilings, ledges, trash cans, towel dispensers).

2. Begin the collection without delay after the donor arrives at the collection site. Do not wait because the donor is not ready or states that he or she is unable to urinate. See Section E

below for instructions on what to do when a donor is unable to provide a specimen.

3. Verify the donor's identity (see Chapter 6).

4. Describe the single specimen or split specimen collection procedure to the donor by reviewing the instructions on the back of the Federal CCF.

5. Complete the collector's portion of the Federal CCF (See Chapter 5).

- Ensure that the pre-printed specimen identification number on the Federal CCF matches the identification number on the specimen bottle label(s)/seal(s).

- Verify any pre-printed urine collection demographic information in Step 1 of the Federal CCF (i.e., information printed by the form supplier).

- If the information is not pre-printed, record the information in Step 1 of the Federal CCF to include:

    - The employer's name, address, telephone and fax number, employer ID number as applicable,

    - The specific MRO name, address, telephone and fax number,

    - Donor SSN or employee ID number,

    - Reason for test,

    - Drug test to be performed, and

    - Collection site information.

6. Ask the donor to:

- Remove any unnecessary outer clothing (e.g., coat, jacket, hat, etc.)

    - The donor must <u>not</u> be asked to remove other articles of clothing, (e.g., shirts, pants, dresses, undergarments) or to remove all clothing and wear a hospital or examination gown.

    - It is <u>not</u> necessary for the donor to remove the following items, unless the collector suspects that they are concealing something that may be used to adulterate or substitute a specimen:

        - Work boots or cowboy boots, or

        - A hat or head covering that the donor refuses to remove based on religious practice.

- Leave other personal belongings (e.g., briefcase, purse) with the outer clothing. The donor may retain his/her wallet.

- To safeguard a donor's belongings, procedures may be established to secure the items during the collection. These may include:

    - An itemized receipt for belongings left with the collector,

    - Storage in a lockable cabinet, or

    - An envelope, box, or container secured with tamper-evident tape.

- Empty his or her pockets and display the items to ensure that no items are present that could be used to adulterate the specimen.

    - If there are no items that can be used to adulterate a specimen, instruct the donor to return the items to the pockets and continue the collection procedure. Go to Step 7.

    - If an item is found that appears to have been brought to the collection site with the intent to adulterate the specimen, use a direct observed collection procedure (see Chapter 7, Section D).

    - If an item that could be used to adulterate a specimen appears to have been inadvertently brought to the collection site, secure the item and continue with the normal collection procedure. Go to Step 7.

    - If the donor refuses to display the items in his or her pockets, discontinue the collection. This is considered a refusal to test (see Chapter 8, Section B).

7. Instruct the donor to wash and dry his or her hands under your observation and <u>not</u> to wash his or her hands again until after delivering the specimen to you and watching the single specimen or split specimens being sealed with the label(s)/seal(s).

    - Liquid soap is preferable. The donor may use bar soap, but bar soap gives the donor the opportunity to conceal soap shavings under his or her fingernails that may be used to attempt to adulterate the specimen.

    - The donor must not be allowed any further access to water or other materials that could be used to adulterate/dilute the specimen.

8. Allow the donor to select the collection kit or collection container (if it is separate from the kit) from the available supply.

9. Unwrap or break the seal of the kit or collection container. You may allow the donor to perform this step.

- Both the collector and the donor must be present.

- Only the seal on the collection container is broken at this time (i.e., the single specimen bottle or split specimen bottles remain sealed/wrapped).

10. Direct the donor:

- To enter the restroom used for urine specimen collection with the collection container,

- To provide a specimen of at least 30 mL for a single specimen collection or at least 45 mL for a split specimen collection,

- Not to flush the toilet, and

- To return with the specimen within approximately 4 minutes of completing the void (i.e., longer wait periods may cause the temperature to be out of range and necessitate a direct observed collection).

Note: Both the collector and the donor must maintain visual contact of the specimen from the time the specimen is transferred to the collector until the single specimen bottle or split specimen bottles have been sealed for shipment to the laboratory.

11. When you receive the specimen from the donor, read the temperature strip affixed to or placed on the outside of the collection container.

- Do this within 4 minutes after the void.

- Mark the appropriate box in Step 2 of the Federal CCF:

    - If the temperature is **within the acceptable range** (32°-38°C/ 90°-100°F), mark "Yes" and proceed with the single specimen or split specimen collection procedure. Go to Step 12.

    - If the temperature is **outside the acceptable range**, mark "No" and immediately begin to collect a second specimen using a direct observed collection procedure (see Chapter 7, Section D) and a new collection kit (i.e., a new collection container and a new Federal CCF).

        - Record an appropriate comment on the "Remarks" line of both Federal CCFs (i.e., for the first and second specimens) to indicate why two specimens were collected including a cross reference to the associated specimen identification number.

        - Complete the first specimen collection and send the first specimen and its Federal CCF to the laboratory.

12. Check the specimen **volume** to ensure that the specimen contains the required volume of

urine (**at least 30 mL for a single specimen or 45 mL for a split specimen**).

- **Single Specimen Collection Procedure**

  - When the specimen volume is more than 30 mL and the temperature is within the acceptable range, complete the single specimen collection procedure. Go to Step 13.

  - When the specimen volume is less than 30 mL and the temperature is within the acceptable range, begin a second single specimen collection procedure using either the original or a new Federal CCF. Go to Step 9.

  - When the temperature is outside the acceptable range, submit the first specimen collected and begin a second single specimen collection procedure using a direct observed collection procedure (see Chapter 7, Section D). Then proceed with Step 11.

- **Split Specimen Collection Procedure**

  - When the specimen volume is more than 45 mL and the temperature is within the acceptable range, complete the split specimen collection procedure. Go to Step 13.

  - When the specimen volume is between 30 mL and 45 mL and the temperature is within the acceptable range, complete the collection procedure as a single specimen collection procedure (i.e., the donor forfeits the right to a split specimen collection. Go to Step 13.

  - When the specimen volume is less than 30 mL and the temperature is within the acceptable range, begin a second split specimen collection procedure using either the original or a new Federal CCF. Go to Step 9.

  - When the temperature is outside the acceptable range, submit the first specimen collected and begin a second split specimen collection procedure using a direct observed collection procedure (see Chapter 7, Section D). Then proceed with Step 11.

- **When a second specimen must be collected**

  - Record an appropriate comment on the "Remarks" line of both Federal CCFs (i.e., for the first and second specimens) to indicate why two specimens were collected including a cross reference to the associated specimen identification number.

  - You may give the donor a reasonable amount of fluid to drink prior to the second collection. The fluid is to be distributed reasonably through a period of **up to three hours** or until the donor has provided a sufficient amount of urine for the second specimen, whichever occurs first.

  - You are <u>not</u> permitted <u>under any circumstances</u> to collect and add or combine urine

from two separate voids.

- o If the donor refuses to provide a second specimen, this is considered a refusal to test (see Chapter 8, Section B).

13. Inspect the specimen for adulteration or substitution by examining the physical characteristics of the urine.

- Note any abnormal characteristics such as:
  - o Unusual color (e.g., specimen is blue),
  - o Presence of foreign objects or material,
  - o Unusual odor (e.g., bleach), or
  - o Signs of adulteration (e.g., excessive foaming when shaken).
- If you observe any abnormal characteristic(s) that appear to be due to adulteration or substitution by the donor, immediately begin a second specimen collection using a direct observed collection procedure (see Chapter 7, Section D).
  - o Record an appropriate comment on the "Remarks" line of both Federal CCFs (i.e., for the first and second specimens) to indicate why two specimens were collected including a cross reference to the associated specimen identification number.
  - o Complete the first collection as described below and send the first specimen and its Federal CCF to the laboratory regardless of whether the first specimen had insufficient volume for either a single or split specimen collection.
  - o If the donor fails to provide at least 45 mL for the second specimen collected, submit the second specimen as a single specimen collection **regardless of the volume**.

14. Unwrap the sealed specimen bottle(s) in the donor's presence. (There will be two specimen bottles to be unwrapped/opened for a split specimen collection.)

15. Fill the specimen bottle(s) from the specimen container and secure the lid/cap on each bottle.

- For a split specimen collection, pour at least 30 mL into the "A" Bottle and at least 15 mL into the "B" bottle), and
- Discard any excess urine remaining in the collection container after the bottle(s) have been filled with the appropriate volumes of urine.

16. Place the appropriate tamper-evident label/seal over the lid/cap of each bottle to ensure that the lid/cap cannot be removed without destroying the label/seal.

- **The donor must observe the sealing of the specimen bottle(s).**

17. Write the date on the tamper-evident label(s)/seal(s).

18. Ask the donor to initial the bottle label(s)/seal(s), using care to avoid damaging them.

- If the donor fails or refuses to initial the seal(s), note this on the "Remarks" line of the Federal CCF and complete the collection process. This is not considered a refusal to test.

- If the tamper-evident label/seal from the Federal CCF does not adhere properly to the specimen bottle (e.g., due to moisture, temperature, specimen bottle material) or is accidentally broken or damaged during the collection process:

  - Apply the unacceptable label/seal to the bottle, and

  - Apply a second, separate tamper-evident label/seal to seal the specimen bottle.

    - Place the additional label/seal perpendicular to the Federal CCF label/seal, to avoid obscuring information on the Federal CCF label/seal,

    - Initial and date the seal,

    - Ask the donor to initial the seal, and

    - Provide a comment on the "Remarks" line of the Federal CCF explaining why the second seal was used.

- If the tamper-evident label/seal from the Federal CCF is broken on the specimen bottle after the donor leaves the collection site**, the collection must be cancelled.**

  - Notify the agency's designated representative that the seal was broken on the specimen bottle.

19. Inform the donor that it is not necessary for him or her to continue observing the collection procedure after the bottle(s) have been sealed, and that he or she is allowed to wash his or her hands.

20. Assist the donor in completing the donor portion of the Federal CCF:

- Instruct the donor to read the donor certification statement in Step 5 (Copy 2) of the Federal CCF.

- Instruct the donor to complete the donor portion of the Federal CCF,

  - Sign and date the certification statement,

- Provide his or her date of birth,
- Print his or her name, and
- Provide day and evening contact telephone numbers.

- If the donor refuses to sign the form or to provide the other information, make a comment on the "Remarks" line of the Federal CCF to that effect. At a minimum, print the donor's name in the appropriate place. **Note:** This does not constitute a refusal to test.

21. Complete the collector chain of custody portion of the Federal CCF (Copy 1, Step 4):

- Print your name,
- Sign where indicated,
- Record the date and time of the collection, and
- Record the specific name of the delivery service to which the specimen bottle(s) are being released.

22. Separate Copy 1 of the Federal CCF from the other four copies and place it and the specimen bottle(s) inside the appropriate pouches of the leak-resistant plastic bag and seal the bag.

23. Separate Copy 5 of the Federal CCF and give it to the donor.

- Suggest that the donor list any prescription and over-the-counter medications he or she may be taking on the back of the donor's copy (Copy 5) of the Federal CCF. This information may help the donor to remember what medications he or she may have taken if a positive result is reported by the laboratory to the MRO. This information must not be recorded on any other copy of the Federal CCF or on the "Remarks" line of the Federal CCF.

24. Inform the donor that he or she may leave the collection site.

25. Prepare the sealed tamper-resistant plastic bag containing the specimen bottle(s) and Federal CCF for transport to the laboratory.

- Place specimens that are to be shipped into a shipping container (e.g., box, express carrier mailer). Several specimen bags may be placed into one shipping container.
- For specimens that will be hand-delivered from the collection site to the laboratory, it is not necessary to use a sealed shipping container. The courier must handle the specimen bags in a manner that protects the specimens from damage.

26. Send Copy 2 of the Federal CCF to the MRO and Copy 4 of the Federal CCF to the agency's designated representative **within 24 hours or during the next business day**.

- Acceptable transmission methods include:
  - Faxing to a secure fax machine,
  - Scanning the image and sending it to a secure computer, and
  - Mailing or transporting by courier.
- The transmission process must be coordinated between the collection site and the MRO to ensure that transmission procedures meet the MRO's or Federal agency's requirements.

27. Submit the specimen to the laboratory as soon as possible **(i.e., no later than 24 hours after the collection or during the next business day).**

- If the specimen is not shipped immediately, the collector is responsible for ensuring its security.
  - For specimens that are in a sealed plastic bag that have not been placed in a shipping container, take necessary steps to prevent any possible tampering or access by unauthorized personnel.
  - For specimens in a sealed shipping container, take necessary steps to protect the container from any possible damage or theft prior to pick-up by the designated delivery service.

D. Direct Observed Collection

A direct observed collection procedure may only be used when:

1. A Federal agency has authorized a direct observed collection because a donor's previous drug test result was reported by an MRO as drug positive, negative and dilute, adulterated, substituted, or invalid, or

2. An immediate collection of a second urine specimen is required in one of the following situations:

- The temperature of the specimen collected during a routine collection is outside the acceptable temperature range.
- There is an indication that the donor has tampered with the specimen (e.g., abnormal physical characteristic such as unusual color, excessive foaming when shaken, unusual odor).

- The donor has intentionally brought to the collection site an item that could be used to:
    - Adulterate (e.g., a small vial containing a suspicious liquid),
    - Substitute (e.g., a small vial containing water or other liquid), or
    - Dilute a urine specimen.

Before conducting a direct observed collection, the collector **must** make the agency representative aware that a situation exists warranting a direct observed collection and explain to the donor why a direct observed collection is being conducted. If the donor declines to allow a direct observed collection when one of the above circumstances has occurred, it is considered a refusal to test (see Chapter 8, Section B).

The procedure for a direct observed collection is the same as that for a routine collection except an observer watches the donor urinate into the collection container. At the point in a routine collection where the donor enters the restroom with the collection container (see Section C, Step 10), a direct observed collection includes the following additional steps:

- The observer must be the same gender as the donor. **There are no exceptions to this requirement.** The individual serving as the direct observer enters the restroom with the donor.
- The observer must directly watch the urine go from the donor's body into the collection container. The use of mirrors or video cameras is not permitted.
- With regard to chain of custody, the observer must never touch or handle the collection container unless the observer is also serving as the collector.
    - The collector may serve as the observer when the collector is the same gender as the donor. If not, the collector must call upon another individual (who is the same gender as the donor) to act as the observer.
- After the donor has completed urinating into the collection container:
    - The donor and observer leave the restroom and the donor hands the collection container directly to the collector,
    - The observer must maintain visual contact of the collection container until the donor hands the container to the collector, and
    - If the same individual serves as direct observer and collector, he or she may receive the collection container from the donor while they are both in the restroom.
- The collector checks the box for an observed collection in Step 2 on the Federal CCF, and provides the name of the observer and the reason for an observed collection on the "Remarks" line in Step 2 of the Federal CCF. A separate sheet explaining the use of an

observed collection may be attached to the Federal CCF if there is insufficient room on the "Remarks" line.

- The collector continues with the routine collection procedures (see Section C, Step 11).

E. Shy Bladder

The term "shy bladder" is used when an individual is unable to provide a specimen either upon demand or when someone is nearby during the attempted urination. The HHS Guidelines specify procedures to follow when a donor claims he or she cannot provide a specimen. If a donor tells the collector, upon arrival at the collection site, that he or she cannot provide a specimen, the collector must still begin the collection procedure regardless of the reason given.

At the point in the collection procedure where the collector and donor unwrap/open the collection container (see Section C, Step 9), the collector does the following:

1. Request that the donor go into the restroom and try to provide a specimen. The donor demonstrates his or her inability to provide a valid specimen when he or she comes out of the restroom with an empty collection container.

2. Begin a "Shy Bladder" collection procedure:

   - The donor is given a reasonable amount of fluid to drink distributed reasonably through a period of up to 3 hours, or until the donor has provided a sufficient amount of urine, whichever occurs first.

   - The donor must remain under the direct observation of the collector to prevent the donor from possibly compromising the collection process.

   - If the donor refuses to attempt to provide a specimen or leaves the collection site before the collection process is completed, the collector must discontinue the collection, record a "refusal to test" on the "Remarks" line of the Federal CCF, and immediately notify the agency's designated representative of the situation.

   - If the donor declines to drink fluids, it is not a refusal to test.

   - **Under no circumstances can a collector combine specimens collected from separate voids to create one specimen of sufficient volume.**

3. Instruct the donor to let you know when he or she is able to provide a sufficient quantity of specimen. It is recommended that you allow sufficient time to have only one additional attempt rather than having to document several unsuccessful attempts. Be sensitive to how frequently you ask a donor to attempt to provide a specimen.

4. Record the time of each attempt to provide a sufficient volume of specimen.

5. If the donor is unable to provide a sufficient volume of specimen in **three hours** from the time the donor first demonstrated that he or she was unable to provide a sufficient volume of

specimen, **discontinue the collection** and:

- Notify the agency's designated representative of a potential "shy bladder" situation,
- Write "Shy Bladder" on the "Remarks" line of the Federal CCF,
- Attach a copy of the record documenting the attempts to collect a specimen, and
- Distribute the copies of the Federal CCF as required.
    - Give Copy 5 to the donor,
    - Discard Copy 1 (no valid specimen was collected), and
    - Send Copy 2 to the MRO and Copy 4 to the agency's designated representative within 24 hours or the next business day.

Chapter 8. Miscellaneous Collection Issues

A. Donor Conduct

The collector should pay close attention to the donor's conduct during the entire collection process and take the following actions as necessary:

1. If the donor's actions or items on his/her person clearly indicate an attempt to substitute or adulterate a specimen conduct a direct observed collection and document the reason on the "Remarks" line of the CCF.

2. If the donor's actions clearly indicate an attempt to substitute or adulterate a specimen and the donor has already provided a specimen:
    - Complete the collection procedure for that specimen and immediately begin a new collection using a direct observed collection procedure, a second Federal CCF, and a new collection kit.
    - Provide appropriate comments in Step 2 on both Federal CCFs (i.e., for the first and second specimens):
        - Note on the "Remarks" line whether the specimen is the first or the second of the two collections for the donor,
        - Write on the "Remarks" line the specimen ID number of the associated specimen,
        - Note on the "Remarks" line the reason for the second collection (i.e., the observed conduct or found items indicative of attempted adulteration/substitution), and

- Document that the second collection was under direct observation by checking appropriate box.

- Inform the agency's designated representative that a collection took place under direct observation and the reason for having done so.

3. If the donor fails to arrive at the assigned time or if the donor fails to remain present through the completion of the collection:

   - Contact the agency's designated representative to obtain guidance on the action to be taken.

   - This is ***not*** considered a refusal to test.

B. Refusal to Test

A Federal agency will take adverse action against an employee whose drug test specimen is reported as a "refusal to test." The collector reports a "refusal to test" when:

1. The donor refuses to display the items in his or her pockets at the beginning of the inspection,

2. The donor declines to allow a direct observed collection when required, or

3. The donor declines to continue the collection process when his or her first specimen has insufficient volume.

When reporting a "refusal to test," the collector must:

1. Notify the agency's designated representative by telephone as soon as possible,

2. Document the refusal to test on the Federal CCF, and

3. Send all copies of the Federal CCF to the Federal agency's designated representative.

Chapter 9. Collector Errors

The Federal CCF is a forensic document and will be part of the litigation package if a specimen comes under legal challenge. The collector should **never** overwrite or scribble out information recorded or printed on the Federal CCF. Unclear or improper edits to Federal CCF information (e.g., donor identification numbers, signatures) could compromise the legal defensibility of the document.

If the collector makes an error on a CCF, he or she should:

1. Make a line through the erroneous information, leaving the original information legible,

2. Write the correct information near (e.g., beside) the original annotation, and

3. Initial and date the change.

It is acceptable for the collector to cross out preprinted information on the Federal CCF that is incorrect or inapplicable (e.g., collection site, MRO, laboratory, or employer information). The collector must use the procedures described above for editing the form. This may be necessary in the event of unexpected collections (e.g., post-accident) or when Federal CCFs at the collection site have outdated information (i.e., the collection site has not yet received Federal CCFs with updated information).

There are three categories of collector errors:

1. Fatal flaws that result in a laboratory rejecting a specimen for testing or that result in an MRO canceling a test,

2. Correctable flaws that result in a laboratory rejecting a specimen for testing or an MRO canceling a test unless the flaw is corrected by a memorandum from the collector, or

3. Omissions and discrepancies on the Federal CCF that are considered insignificant and do not cause rejection by the laboratory or cancellation by the MRO when they are infrequent (i.e., when a collector does not make the error more than once a month).

The collector must take **immediate** steps to provide a memorandum for the record to the laboratory or MRO when notified of an error. A laboratory holds specimens for a short time (i.e., a minimum of 5 business days) after the collector has been notified, before reporting the specimen as rejected and discarding the specimen.