

**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

EFFECTIVE OCTOBER 1, 2010

Note: This manual applies to Federal agency drug testing programs that come under Executive Order 12564 dated September 15, 1986, section 503 of Public Law 100-71, 5 U.S.C. section 7301 note dated July 11, 1987, and the Department of Health and Human Services Mandatory Guidelines for Federal Workplace Drug Testing Programs (69 FR 19644) dated November 25, 2008 (effective October 1, 2010).

This manual does not apply to specimens submitted for testing under U.S. Department of Transportation (DOT) 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 the person who instructs and assists donors at a collection site and receives the specimen provided by the 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 supervisor serving as a collector must be a trained collector.
- The hiring official of an applicant may not serve as the collector when the applicant is tested, unless there is no feasible alternative. A hiring official serving as a collector must be a trained collector.
- A co-worker who is in the same testing pool or who works with an employee on a daily basis must not serve as a collector when that employee is tested.
- An applicant or employee must not serve as the collector by collecting his or her own specimen.
- An individual working for an HHS-certified Instrumented Initial Test Facility (IITF) or laboratory may not serve as a collector if that individual can link the donor with the specimen drug test result or the report from the test facility (IITF or laboratory).
- An individual who has a personal relationship with the employee (e.g., spouse, ex-spouse, relative, close personal friend) must not serve as the collector.

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 (Mandatory Guidelines)
- Read and understand any guidance provided by the Federal agency which is consistent with the Mandatory Guidelines
- Receive training from a qualified trainer for collectors on the following topics:
 - The steps to correctly perform a collection, including the proper completion and distribution of the Federal CCF
 - Problem collections
 - Fatal and correctable flaws and how to correct problems in collections
 - Collector responsibilities to maintain the security and integrity of specimens, to protect the privacy of donors, and to maintain proper conduct

- Demonstrate proficiency in collections by successfully completing five consecutive error-free mock collections that include: two uneventful scenarios, one insufficient specimen scenario, one where the temperature is out of range, and one in which the donor refuses to sign the Federal CCF and refuses to initial the tamper-evident bottle label/seal
 - The qualified trainer for collectors must monitor and evaluate the individual and must attest that the mock collections are error-free
- Complete refresher training on the items above at least every five years from the date of initial training
- Have documentation that he or she has completed training as a collector in accordance with the above requirements (i.e., before collecting any specimens for a Federal agency)
- Maintain training documentation and provide it to a Federal Agency upon request

The collector should have identification with his or her name and his or her employer's name, address, and telephone number. The collector is required to provide his or her identification (employee badge or employee list) 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.

To qualify as an observer for a direct observed collection for a Federal agency program, an individual must:

- Be knowledgeable of the direct observed collection procedure as described in the Mandatory Guidelines
- Be knowledgeable of any guidance provided by the Federal agency or by HHS relating to the direct observed collection procedure described in the Mandatory Guidelines
- Receive training on the following subjects: :
 - The steps necessary to perform a direct observed collection correctly
 - Maintain the integrity and security of the specimen throughout the collection process by maintaining visual contact with the collection container
 - Ensure the privacy of the donor
 - Ensure that the observation is done in a professional manner, to minimize discomfort of the donor
 - Avoid conduct that can be interpreted as offensive or inappropriate
- Be the same gender as the donor. **There are no exceptions to this requirement.**

An observer is not required to be a trained collector.

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

- Be qualified as a trained collector and have regularly conducted drug test collections for at least one year, OR have successfully completed a “train the trainer” course given by an organization (e.g., manufacturer, private entity, contractor, or Federal Agency)
- Undergo refresher training in accordance with collector requirements (see above) at least every five years from the date of the individual's initial training
- Maintain documentation of his or her training and provide it to a Federal Agency upon request.

Before an individual is permitted to collect a specimen for a Federal Agency, the agency must:

- Ensure that the individual meets the collector requirements described in the Mandatory Guidelines
- Ensure that the individual or a third party (e.g., third party administrator, collector training organization, Federal agency that employs its own collectors) has a copy of the individual's collector training documentation
- Provide the individual with the name and telephone number of the Federal agency's designated representative to contact in the event that any problems or issues arise during a collection

Chapter 2. Collector/Collection Site Records

The collector should maintain his or her original collector training records (i.e., for initial and refresher training) and should provide copies to his or her employer and, as requested, to the Federal agency. Collection site records must be stored for a minimum of two years. This includes the collector copy (Copy 3) of the Federal CCF for each specimen. Collection records must be stored and disposed of in a manner that ensures donor confidentiality is maintained.

Chapter 3. The Collection Site

A collection site is a permanent or temporary facility where donors present themselves for the purpose of providing a specimen for a drug test. When there is an immediate need to collect a specimen (e.g., a post-accident situation) and there is no agency-designated site available, a collection may be conducted in a public restroom. The site must have all necessary personnel, supplies, equipment, facilities, and supervision to provide for specimen collection and security, and for temporary storage until the specimen is transferred to an HHS-certified laboratory or IITF, and must have arrangements for the transfer of the specimens to a certified IITF or

laboratory.

A facility used as a collection site must have:

1. Provisions for donor privacy while he/she provides the urine specimen. The following facilities provide adequate privacy for urine collections:
 - An enclosed stall in a multi-stall restroom
 - A single person restroom
 - A partitioned area that allows for individual privacy
 - A mobile restroom (e.g., a vehicle with an enclosed toilet stall).
2. A means for washing hands:
 - If practical, the water source should be external to the restroom where collection occurs. If a water source is in the enclosure where the collection occurs, the collector must secure it prior to the collection or conduct a monitored collection (see Chapter 7, Sections C and E).
 - If a water source is not available, another means (e.g., waterless cleanser, moist towelettes) outside the restroom is an acceptable alternative.
3. A suitable clean surface, inaccessible to the donor, for the collector to use as a work area:
 - If practical, the collector work area should be external to the restroom where collection occurs.
 - The collector work area may be inside the restroom only if the donor can have privacy while providing the urine specimen.
4. A secure temporary storage area for maintaining specimens until they are transferred to an HHS-certified IITF or laboratory. **Note: Specimens should NOT be exposed to high temperatures for an extended time. These conditions may affect the test results of a urine specimen.**
5. Procedures or restrictions to prevent:
 - Unauthorized access to the site during the collection,
 - Unauthorized access to the collection materials/supplies,
 - Unauthorized access to collection site records, and

- Donor access to items that could be used to adulterate, substitute, or dilute the specimen (e.g., soap, disinfectants, cleaning agents, water).

Chapter 4. Federal Agency Blind Samples

Each Federal agency is required to have blind samples (i.e., negative samples, 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 an IITF or laboratory with an agency's specimens. The Mandatory Guidelines specify the approximate percentage of each type (i.e., 75% negative, 15% positive for one or more drugs, 10% either adulterated or substituted). At a minimum, each Federal Agency must submit 3% blind samples with its donor specimens (i.e., based on the yearly number of donor specimens), and effort should be made for them to be submitted quarterly. The blind samples should be distributed throughout the donor specimens rather than being submitted as one group.

Each blind sample must meet the following requirements:

- Positive and negative samples must be validated by the supplier using the appropriate initial and confirmatory drug tests,
- The shelf life of each blind sample must be provided by the supplier to ensure that the sample is submitted for testing prior to its expiration date,
- Positive blind samples should be 1.5 to 2 times the initial drug test cutoff and contain at least one of the required drugs listed in the Mandatory Guidelines;
- Substituted or adulterated blind samples must demonstrate such characteristics at the time of the validation by the supplier.

Each blind 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 Federal CCF and writes fictitious initials on the specimen bottle label/seal.
- The collector indicates that the sample is a 'blind sample' on the Medical Review Officer (MRO) copy where the donor would normally provide a signature (Step 5 on Copy 2 of the Federal CCF).
- The collector may either discard Copy 5 of the Federal CCF (the donor copy) or maintain it with Copy 3 of the Federal CCF (the collector copy).

If the collector purchases the samples for the Federal agency's blind 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. The

MRO will investigate discrepant results with the supplier and/or collector.

Chapter 5. The Federal Drug Testing Custody and Control Form (Federal CCF)

Federal agencies are required to use an Office of Management and Budget (OMB)-approved Federal CCF when collecting urine specimens for their workplace drug testing programs. Federal CCFs are available from a number of different sources (e.g., IITFs, laboratories, collectors, third party administrators, MROs).

Employers are prohibited from using the Federal CCF for:

- Private-sector employee drug testing programs, other than testing conducted under the Department of Transportation (DOT) regulations
- State workplace drug testing programs
- Department of Justice drug testing programs

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 a Federal CCF), uses a non-Federal form or incorrect Federal CCF for a Federal agency collection:

- The use of the incorrect form does not, in and of itself, constitute a reason for the IITF or laboratory to reject the specimen for testing or for the MRO to cancel the test.
- The collector must send a memorandum for the record (MFR) with the specimen stating the reason why the correct Federal CCF was not used for the Federal agency collection.
- If an IITF, laboratory, or MRO discovers the use of a non-Federal or incorrect Federal form, the collector will be notified to provide an MFR explaining the use of the incorrect form.
- If the collector does not provide an MFR for the record after five business days, the IITF or laboratory will report a rejected for testing result to the MRO who will cancel the test.

All urine specimens must be collected using chain of custody procedures. Chain of custody is the term used to describe the procedures to account for the integrity of each specimen and aliquot (i.e., portion of a specimen used for testing) by tracking handling and storage from the point of specimen collection to final disposition of the specimen and its aliquots. For specimens collected under the Mandatory Guidelines, the collector begins the chain of custody documentation at the collection site using a Federal CCF.

The **2010 Federal CCF** has an **effective date of October 1, 2010**.

The **2000 Federal CCF** was published in the Federal Register on June 23, 2000 (65 FR 39155), with an **effective date of August 1, 2000**. To allow for depletion of existing supplies of the 2000 Federal CCF's, OMB permitted the use of the 2000 Federal CCF in Federal workplace drug testing programs **through September 30, 2011**. Therefore, for one (1) year after the implementation of the 2010 Federal CCF on October 1, 2010, regulated specimens may be collected, tested, and reported using the 2000 Federal CCF.

As of October 1, 2011, the 2010 Federal CCF will be the only Federal CCF for regulated specimens. If a regulated specimen is received at a test facility accompanied by the 2000 Federal CCF after September 30, 2011, the test facility (IITF or laboratory) must treat this as a correctable flaw and require an MFR from the collector, or the specimen may be rejected by the test facility and canceled by the MRO (see procedures above regarding a collector's use of a non-Federal form or incorrect Federal CCF).

Links to both the **2010 Federal CCF** and the **2000 Federal CCF** are on the SAMHSA website <http://www.workplace.samhsa.gov/>

A. Federal CCF Description: 2010 Federal CCF and 2000 Federal CCF

Both are five-part forms and the function of each copy is the same:

Copy 1 - Test Facility Copy – sent to the IITF or laboratory with the specimen bottles

Copy 2 - MRO Copy – sent to the MRO

Copy 3 - Collector Copy – retained by the collector

Copy 4 - Employer Copy – sent to the Federal agency

Copy 5 - Donor Copy – given to the donor when the collection process is complete

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

- A specific IITF or 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
- A corporate name and telephone number (the IITF or laboratory that receives the specimen for testing will annotate its address)

The bottom of Copy 1 is reserved for the tamper-evident specimen bottle labels/seals:

- There must be two labels/seals: one marked with the letter "A" to designate the primary specimen and the other marked with the letter "B" to designate the split specimen.

- Each label/seal must have:
 - The same preprinted specimen identification number that is printed at the top of the Federal CCF,
 - A place for the collector to annotate the date of the collection, and
 - A place for the donor to initial each label after it is placed on the specimen bottles.

B. Instructions for Use: 2010 Federal CCF

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 collection site and collector information may be preprinted or handwritten,
- The collector enters the donor's identification (e.g., social security number or employee I.D. number) after verifying the donor's identity,
- The testing authority box is marked to indicate under which Federal agency the specimen is being collected,
- The appropriate box is marked to indicate the reason for the test, and
- The appropriate box is marked for the drug tests to be performed. If the test is to be performed for a drug other than the five drug classes printed on the Federal CCF, the Federal Agency must provide an explanatory MFR to the collector. The collector must attach the MFR to the Federal CCF prior to packaging the specimen for shipment to the test facility.

Step 2. To be completed by the collector after receiving the specimen from the donor and measuring the temperature of the specimen within 4 minutes. 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 (note: split specimens are required for all Federal agency collections),
- 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:

- Place the labels/seals on the primary and split specimen bottles,
- Date the labels/seals,
- Have the donor initial the label/seal on each bottle (i.e., after the labels/seals have been placed on the bottles), and
- Have the donor complete Step 5 on Copy 2 (the MRO copy). 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. If the donor refuses to sign the certification statement, the collector enters a remark in Step 2 on Copy 1.

The collector does not make any entries on Copy 2. The MRO will complete Copy 2 entries.

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

- Sign the collector certification statement in Step 4 on Copy 1 to certify that the specimen was collected, labeled, sealed, and released for shipment to the IITF or laboratory in accordance with Federal requirements.
- Print his or her name.
- Record the following:
 - Date of collection
 - Time of collection
 - The specific name of the delivery service to which the specimen is released for shipment to the IITF or laboratory.
 - There is no requirement for couriers, express carriers, or postal service personnel to document chain of custody for specimens during transit because

they do not have access to the specimen bottles or the Federal CCF.

The collector does not make entries below the first bold line in Step 4. Copy 1 entries in Step 4 below the first bold line and in the following Steps are made at the HHS-certified IITF or laboratory:

C. Instructions for Use: 2000 Federal CCF

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 collection site 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, and
- The appropriate box is marked for the drug tests to be performed. If the test is to be performed for a drug other than the five drug classes printed on the Federal CCF, the Federal Agency must provide an explanatory MFR to the collector. The collector must attach the MFR to the Federal CCF prior to packaging the specimen for shipment to the test facility.
- The employer, Federal agency representative, or collector should write the testing authority (i.e., HHS, NRC, specific DOT agency, USCG) in Step 1. Note: No action is taken by the MRO if this information is omitted.

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). 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. If the donor refuses to sign the certification statement, the collector enters a remark in Step 2 on Copy 1.

The collector does not make any entries on Copy 2. The MRO will complete Copy 2 entries.

Step 4. To be initiated by the collector and completed at the test facility. 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.

The collector does not make entries below the first bold line in Step 4. Copy 1 entries in Step 4 below the first bold line and in the following steps are made at the HHS-certified IITF or laboratory.

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, or any other picture identification issued by a Federal, state, or local government agency),
- Identification by the supervisor of the donor or by a Federal agency representative, or
- Other identification allowed under a Federal agency's workplace drug testing plan.

If the identity of the donor cannot be established, the collector stops the collection.

Unacceptable forms of identification are:

- Identification by a co-worker,
- Identification by another donor,
- Non-photo identification (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.

Chapter 7. Urine Specimen Collection**A. 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.

A collector must:

- Prohibit unauthorized personnel from entering the collection site during the collection;
- Perform only one specimen collection at a time;
- Restrict access to collection supplies before and during the collection;
- Ensure that only the collector and the donor are allowed to handle the unsealed specimen;
- Ensure that chain of custody is maintained and documented throughout the collection procedure,

- Ensure that Copy 1 of the Federal CCF is enclosed with the specimen and sealed for shipment to the IITF or laboratory; and
- Ensure that specimens are transported to the test facility in a sealed and secure shipping container to eliminate the possibility of damage during shipment and to prevent undetected tampering.

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 not substantially affect the specimen collected and must be:
 - Supplied as an individually sealed item using a tamper-evident system (e.g., in a sealed plastic bag, shrink wrapped, with a peelable or sealed lid, or another easily visible tamper-evident system),
 - Large enough to easily catch and hold at least 55 mL of urine, and
 - Graduated with volume markings clearly showing the volume (e.g., 45 mL).
2. **Single-use plastic specimen bottles.** Each specimen bottle with cap must not substantially affect the specimen collected and must be:
 - Supplied as individually sealed bottles with a tamper-evident system (e.g., using plastic bag, shrink wrap, with a peelable or sealed lid, or another easily visible tamper-evident system),
 - Able to hold at least 35 mL,
 - The split specimen bottle may be the same size as or smaller than the primary specimen bottle, but must be able to hold at least 20 mL.
 - Leak-resistant (i.e., have a screw-on or snap-on cap that prevents 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 must accurately measure the temperature of the specimen and not contaminate the specimen. The strips may be affixed

to the collection container as supplied or placed on the collection container after the donor gives the collection container with the specimen to the collector.

4. **Federal CCFs.** An OMB-approved Federal CCF as described in Chapter 5.
 5. **Tamper-evident seals.** The Federal CCF has two tamper-evident labels/seals that are used to seal the specimen bottles (i.e., primary and split specimens). 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 another tamper-evident seal.
 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 inside the leak-resistant plastic bag with the specimen bottles 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 an IITF or laboratory must be securely sealed to prevent the possibility of undetected tampering. It is not necessary to use a shipping container/mailed if a courier hand-delivers the sealed leak-resistant plastic bags containing the specimen bottles directly from the collection site to the IITF or 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 bottles 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).
- Note: Specimens should NOT be exposed to high temperatures for an extended time. These conditions may affect the test results of a urine specimen.**
11. **Disposable gloves.** HHS recommends that collectors use single-use disposable gloves while handling specimens. The Occupational Safety and Health Administration has specific standards addressing protection of employees who are exposed to potentially infectious body fluids (29 CFR Part 1910.1030).

C. Collection Procedure

1. Prepare the collection site to collect urine specimens:
 - Assemble supplies.
 - Ensure that there is bluing agent in the toilet. If no bluing agent is available or if there is an automatic flushing system, turn off the water supply and flush the toilet to remove any water in the toilet when possible.
 - Turn off the water supply or secure water sources inside the restroom.
 - The collector must provide a means for the donor to wash his or her hands before and after the collection. The collector must secure the water source after the donor washes his or her hands and restore the water supply after the collection, or provide another means (e.g., waterless cleanser, moist towelette).
 - If a water source inside the restroom cannot be turned off or secured, the collector must perform a monitored collection as described in Chapter 7, Section E below.
 - 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. If a donor does not arrive at the collection site at the assigned time for the drug test, contact the Federal Agency representative to obtain guidance on the appropriate action to be taken.
3. Begin the collection without delay when the donor arrives at the collection site. Do not wait because an authorized employer or Federal agency representative is late in arriving or because the donor states that he or she is not ready or is unable to urinate. **If the donor states that he or she is unable to provide a urine specimen, continue with the collection procedure through Step 11 below.**
4. Verify the donor's identity (see Chapter 6).
5. Describe the basic collection procedure to the donor and instruct the donor that he or she may read the instructions for completing the Federal CCF (on the back of the Federal CCF).
6. Answer any reasonable and appropriate questions that the donor has about the collection process.
7. 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 labels/seals.
 - Verify any urine collection demographic information in Step 1 of the Federal CCF (i.e., information printed or annotated by the form supplier).

- If the information is not present, record the information in Step 1 of the Federal CCF to include:
 - The employer's name, address, telephone and fax numbers, and employer ID number (if applicable),
 - The specific MRO name, address, telephone number, and fax number,
 - Donor identification (SSN or employee ID number),
 - Specific testing authority for the Federal agency drug test (if known),
 - Reason for test,
 - Drug test to be performed,
 - Collection site address, and
 - Collector telephone and fax numbers.

8. Ask the donor to:

- Remove any unnecessary outer clothing (e.g., coat, jacket, hat, etc.).
 - The donor must not 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 not 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 or 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 (i.e., with access controlled by the donor) 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 9.
 - 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 9.
 - If the donor refuses to display the items in his or her pockets, stop the collection. This is considered a refusal to test (see Chapter 8, Section B).
9. Instruct the donor to wash and dry his or her hands under your observation.
- Liquid soap is preferred over bar soap, because bar soap gives the donor the opportunity to conceal soap shavings under his or her fingernails in an attempt to adulterate the specimen.
 - After washing his or her hands, the donor must remain in the collector's presence and not be allowed access to any water fountain, faucet, soap dispenser, cleaning agent, or other materials which could be used to adulterate, substitute, or dilute a specimen.
10. Give the donor or allow the donor to select the collection kit or collection container (if it is separate from the kit) from the available supply.
11. 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 specimen bottles remain sealed/wrapped).

Note: If the donor has stated that he or she is unable to provide a specimen, at this point in the collection, request that the donor enter the restroom and attempt to provide a specimen. If the donor comes out of the stall with an empty collection container, he or she has demonstrated the inability to provide a specimen. Follow the Insufficient Specimen procedure in Chapter 7, Section F.

12. Direct the donor to:

- Take the collection container into the restroom/stall to be used for the collection,
- Provide a specimen of at least 45 mL,
- Not flush the toilet, and
- Return with the specimen as soon as he or she has finished completing the void.
 - You may inform the donor that the temperature of the urine specimen must be read within 4 minutes after the void to be valid. Longer wait periods may cause the temperature to be out of range and necessitate an observed collection.
 - A reasonable time limit may be set for completing the void.

Note: Neither the collector nor anyone else may go into the restroom with the donor, except in the case of a direct observed collection (see Chapter 7, Section D) or a monitored collection (see Chapter 7, Section E).

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

Note: After receiving the specimen from the donor, whenever practical, the collector may allow the donor to wash his or her hands and to flush the toilet. (The collector may inspect the toilet for any materials indicative of specimen tampering prior to flushing.)

13. 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 collection procedure. Go to Step 14.
 - If the temperature is **outside the acceptable range**, mark “No” and perform a second, directly observed collection:
 - Complete the first collection before initiating the second collection, including Step 14 (examining the physical characteristics of the urine, noting any abnormal characteristics in the Remarks line of the Federal CCF), and continuing with the procedure in Step 16.
 - Record an appropriate comment on the Remarks line in Step 2 of the Federal CCF for the first specimen to indicate why two specimens were collected, including a cross reference to the specimen identification number of the second

specimen.

- Begin the collection of 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 in Step 2 of the Federal CCF for the second specimens to indicate why two specimens were collected, including a cross reference to the specimen identification number of the first specimen.

Note: The first specimen and its Federal CCF are sent to an HHS-certified laboratory regardless of the specimen volume.

Note: Both the first and second specimens must be sent to an *HHS-certified laboratory* for testing (i.e., not to an IITF).

Note: If the donor refuses to provide a second specimen or leaves the collection site before the collection process is completed, this is considered a refusal to test (see Chapter 8, Section B).

14. Inspect the specimen for adulteration or substitution by examining the physical characteristics of the urine.
 - Note any abnormal characteristics such as:
 - Unusual color (e.g., specimen is blue),
 - Presence of foreign objects or material,
 - Unusual odor (e.g., bleach), or
 - Signs of adulteration (e.g., excessive foaming when shaken).
 - A specimen suspected of not being a valid urine specimen must be sent to an HHS-certified laboratory for testing (i.e., not to an IITF).
 - 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) and a new collection kit (i.e., a new collection container and a new Federal CCF).
 - Record an appropriate comment on the Remarks line in Step 2 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 collection by continuing with the procedure in Step 16.

15. Check the specimen volume to ensure that the specimen contains at least **45 mL** of urine.

- If the specimen volume is at least 45 mL, complete the specimen collection procedure continuing with Step 16.

When the specimen volume is less than 45 mL, discard the specimen and immediately begin a second collection using the same procedures and the same Federal CCF. Use a new collection container for the second collection.

Note: If the donor refuses to attempt to provide a second specimen or leaves the collection site before the collection process is completed, this is considered a refusal to test (see Chapter 8, Section B).

- When a second specimen must be collected, follow the Insufficient Volume procedure in Chapter 7, Section F.
 - When the donor hands you the second specimen, continue with the collection procedure, including Step 13 (checking specimen temperature) and Step 14 (examining physical characteristics of the urine).
 - If the donor is unable to provide at least 45 mL for the second specimen after a period of three hours, stop the collection procedure and report the failure to provide a sufficient specimen as described in the Insufficient Volume procedure in Chapter 7, Section F.

16. Unwrap the sealed specimen bottles in the donor's presence.

17. In the donor's presence, pour the urine from the specimen collection container into the specimen bottles and secure the lid/cap on each bottle.

- Pour at least 30 mL into the "A" Bottle and at least 15 mL into the "B" bottle.

18. 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 bottles.**
- 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 seal to seal the specimen bottle.
 - Place the additional seal perpendicular to the Federal CCF label/seal, to avoid obscuring information on the Federal CCF label/seal,

- Initial and date the second seal,
 - Ask the donor to initial the second seal, and
 - Provide a comment on the Remarks line in Step 2 of the Federal CCF explaining why the second seal was used.
19. Discard any excess urine remaining in the collection container after the bottles have been filled with the appropriate volumes of urine.
- The only exception is when the excess urine is being used to conduct clinical tests in conjunction with a physical examination that is required by the Federal agency. No further tests may be conducted on the excess urine.
20. Write the date on the tamper-evident labels/seals.
21. Ask the donor to initial the label/seal on each bottle, using care to avoid damage.
- If the donor fails or refuses to initial the seals, note this on the Remarks line in Step 2 of the Federal CCF and complete the collection process. This is not considered a refusal to test.
22. Inform the donor that it is not necessary for him or her to continue observing the collection procedure after the bottles have been sealed, and that he/she is allowed to wash his or her hands.
23. Assist the donor in completing the donor portion of the Federal CCF:
- Instruct the donor to read the donor certification statement in Step 5 on Copy 2 of the Federal CCF.
 - Instruct the donor to complete the donor portion on Copy 2 of the Federal CCF:
 - Sign and date the certification statement,
 - Provide his or her date of birth,
 - Print his or her name,
 - 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 in Step 2 of the Federal CCF to that effect. At a minimum, print the donor's name where indicated. **Note:** This does not constitute a refusal to test.
24. Complete the collector chain of custody portion Step 4 on Copy 1 of the Federal CCF:

- 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 bottles are being released.
25. Separate Copy 1 of the Federal CCF from the other four copies. Place Copy 1 and both specimen bottles inside the appropriate pouches of the leak-resistant plastic bag and seal the bag. Note: If testing is to be performed for a drug other than the five drug classes printed on the Federal CCF (i.e., the “other” checkbox is marked), the Federal Agency must provide an explanatory MFR to the collector. The collector must attach the MFR to Copy 1 of the Federal CCF to be sent with the specimen to the test facility.)
26. Separate Copy 5 of the Federal CCF and give it to the donor.
- Remind the donor that he or she may list any prescription and over-the-counter medications on a separate sheet or 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 he or she is contacted by the MRO.
- Note: This information must not be recorded on any other copy of the Federal CCF or on the Remarks line of the Federal CCF.**
27. Inform the donor that he or she may leave the collection site.
28. Prepare the sealed tamper-resistant plastic bag containing the specimen bottles and Federal CCF for transport to the IITF or laboratory.
- Place the sealed specimen bag(s) 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 IITF or 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.
 - If the tamper-evident label/seal from the Federal CCF is broken on a specimen bottle after the donor leaves the collection site, **the collection must be cancelled.**
 - Notify the agency’s designated representative that the label/seal was broken on the specimen bottle.
29. 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 after the collection or during the next business day.**

- Acceptable transmission methods include:
 - Faxing to a secure fax machine,
 - Sending a scanned image of the Federal CCF copy 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.

30. Submit the specimen to the IITF or laboratory **within 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 in a sealed plastic bag that has not been placed in a shipping container, take necessary steps to prevent any possible tampering or access by unauthorized personnel.
 - For specimen packages 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, adulterated, substituted, invalid without a legitimate medical reason, or cancelled because the split specimen failed to reconfirm the primary specimen results or could not be tested, or
2. At the collection site, 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 conduct of the donor clearly indicates an attempt to adulterate or substitute the specimen.
- The donor has brought an item to the collection site for the purpose of:
 - Adulteration (e.g., a small vial containing a suspicious liquid),
 - Substitution (e.g., a small vial containing water or other liquid), or
 - Dilution of a urine specimen.

Before conducting a direct observed collection under Item 2 above, the collector must contact a collection site supervisor for concurrence with the collector's decision for 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 (i.e., of the same gender as the donor) 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 12), a direct observed collection includes the following additional steps:

1. The individual serving as the observer enters the restroom with the donor.
 - The observer must be the same gender as the donor. **There are no exceptions to this requirement.**
 - If there is no collector of the same gender as the donor, the collector or collection site supervisor must select another individual to serve as the observer. The individual must meet the HHS Mandatory Guidelines qualifications for an observer (see Chapter 1).
2. 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. If the donor fails to follow the observer's instructions related to the direct observed collection, this is considered a refusal to test (see Chapter 8, Section B).
3. 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.
4. 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 with the collection container until the donor hands the container to the collector, and

- If the same individual serves as both observer and collector, he or she may receive the collection container from the donor while they are both in the restroom.
5. The collector checks the box for an observed collection in Step 2 of the Federal CCF and provides the name of the observer (if applicable) and the reason for an observed collection on the Remarks line in Step 2 of the Federal CCF. If there is insufficient room on the Remarks line, the collector may attach a separate MFR explaining the use of an observed collection to the Federal CCF.
 6. The collector continues with the routine collection procedures (see Section C, Step 13).

E. Monitored Collection

A monitored collection procedure must be used when:

1. The collection is being conducted in a public restroom (e.g., when the Federal agency's designated collection site is not available and there is an immediate need for a collection), or
2. The restroom used for the collection has a water source that cannot be disabled or secured.

If the donor declines to allow a monitored 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 monitored collection is the same as that for a routine collection except an individual monitors the collection by checking for signs that the donor may be tampering with the specimen. At the point in a routine collection where the donor enters the restroom with the collection container (see Section C, Step 12), a monitored collection includes the following additional steps:

1. The monitor accompanies the donor into the restroom, and secures the restroom to ensure that no one else can enter during the collection process.
 - The monitor must be the same gender as the donor, unless the monitor is a trained medical professional (e.g., nurse, doctor, physician's assistant, technologist or technician) who is licensed or certified to practice where the collection occurs.
 - The monitor is not required to be a trained collector.
2. The monitor listens for signs of tampering with the specimen.
 - The monitor must remain in the restroom, but outside the stall while the donor is providing the specimen.
 - The monitor must not watch the donor urinate into the specimen container.
4. If there is evidence of specimen tampering, the monitor notifies the collector to immediately begin to collect a second specimen using a direct observed collection procedure (see

Chapter 7, Section D).

5. With regard to chain of custody, the monitor must never touch or handle the collection container unless the monitor is also serving as the collector.
6. After the donor has completed urinating into the collection container:
 - The donor and monitor leave the restroom and the donor hands the collection container directly to the collector,
 - The monitor must maintain visual contact with the collection container until the donor hands the container to the collector, and
 - If the same individual serves as both monitor and collector, he or she may receive the collection container from the donor while they are both in the restroom.
7. The collector provides the name of the monitor (if applicable) on the Remarks line in Step 2 on Copy 1 of the Federal CCF.
8. The collector continues with the routine collection procedures (see Section C, Step 13).

F. Insufficient Specimen

If a donor tells the collector that he or she cannot provide a specimen, the collector must begin the collection procedure regardless of the reason given. 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. Immediately begin a second collection using the same procedures, the same collection container, and the same Federal CCF.

1. If the donor indicates that he or she may be able to provide a specimen if given more time:
 - Offer the donor a reasonable amount of fluid to drink distributed reasonably through a period of up to 3 hours (e.g., an 8 ounce glass of water every 30 minutes, not to exceed 40 ounces over a period of 3 hours) or until the donor has provided a sufficient amount of urine, whichever occurs first. The donor is not required to drink fluids during the waiting period.
 - 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.
 - Record the time of the attempt to provide a sufficient volume of specimen (e.g., on the Remarks line of the CCF).
 - The donor must remain under the direct observation of the collector to prevent the donor from possibly compromising the collection process.

Note: The collector must NOT under any circumstances combine urine collected from separate voids to create one specimen of sufficient volume.

2. If the donor states that he or she is unable to provide a specimen, or if the donor has not provided sufficient volume of specimen in **three hours** from the time of the donor's first attempt, **discontinue the collection** and:
 - Record the reason for not collecting the specimen on the Remarks line and mark the "None Provided" box in Step 2 of the Federal CCF,
 - Notify the agency's designated representative of the situation,
 - Discard the urine collected (if any),
 - Give Copy 5 of the Federal CCF to the donor and request that the donor leave the collection site,
 - Discard Copy 1 of the Federal CCF (no valid specimen was collected), and
 - Send Copy 2 of the Federal CCF to the MRO and Copy 4 of the Federal CCF to the Federal agency's designated representative within 24 hours or the next business day.
3. If the donor refuses to attempt to provide a specimen or leaves the collection site before the collection process is completed, this is a refusal to test. The collector must follow the procedure in Chapter 8, Section B.

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 or her person clearly indicate an attempt to tamper with (i.e., substitute, adulterate, or dilute) a specimen, conduct a direct observed collection (see Chapter 7, Section D) and document the reason on the Remarks line in Step 2 of the Federal 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 substitution or adulteration), and
 - Document that the second collection was under direct observation by checking the appropriate box and writing the observer's name in the Remarks line (if the collector was not the observer).
 - Inform the Federal 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:
- Contact the Federal 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 fails to cooperate with any part of the testing process (e.g., refuses to provide a specimen, refuses to display the items in his or her pockets at the beginning of the collection, or refuses to wash his or her hands at the beginning of the collection),
2. The donor declines to allow a direct observed collection when required, or fails to follow the observer's instructions related to the direct observed collection,
3. The donor declines to allow a monitored collection when required,
4. The donor declines to continue the collection process when his or her first specimen has insufficient volume,
6. The donor leaves the collection site before completion of the collection (except for leaving before the collection has begun for a pre-employment test).
7. The donor possess or wears a prosthetic device that could interfere with the drug test,

8. The donor admits to the collector that he or she has adulterated or substituted his or her specimen.

When reporting a “refusal to test,” the collector must:

1. Notify the agency’s designated representative by any means (e.g., telephone, secure fax machine, e-mail) that ensures immediate receipt of the refusal notification,
2. Document the refusal to test on the Federal CCF with appropriate comments, signature, and date in the Remarks line of Step 2, 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** use correction fluid on the Federal CCF, and 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 Federal 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, IITF, laboratory, or employer information). The collector must use the procedures described above for changing the information on 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.

There are three categories of collector errors:

1. Fatal flaws that result in an IITF or laboratory rejecting a specimen or an MRO cancelling a test,
2. Correctable flaws that result in an IITF or laboratory rejecting a specimen or an MRO cancelling a test unless the flaw is corrected by an MFR from the collector, or
3. Omissions and discrepancies on the Federal CCF that are considered insignificant and do not cause rejection by the IITF or 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 an MFR to the IITF, laboratory, or MRO when notified of an error. An IITF or laboratory holds specimens for a short time (i.e., a minimum of five business days) after the collector has been notified, before reporting the specimen as rejected for testing and discarding the specimen.

Federal agencies must investigate reported collection site deficiencies (e.g., specimens rejected for testing due to collector errors).