

**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, 2017

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 (82 FR 7920) dated January 23, 2017 (effective October 1, 2017).

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 trained to instruct and assist a donor in providing a specimen.

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 their 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 urine specimen collector for a federal agency program, an individual must:

- Be knowledgeable of the collection procedure described in the HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs (Mandatory Guidelines).
- Be knowledgeable of any guidance provided by the federal agency's Drug-Free Workplace Program and additional information provided by HHS relating to the collection procedure described in the Mandatory Guidelines.
- Receive training from a qualified trainer for urine specimen collectors on the following topics:
 - All steps to correctly perform a urine specimen collection.
 - Completion and distribution of the Federal CCF.
 - Problem collections.
 - Fatal and correctable flaws and how to correct problems during collections.
 - Collector responsibilities to maintain the integrity of the collection process, ensuring the privacy of the donor, ensuring the security of the specimen, and avoiding conduct

or statements that could be viewed as offensive or inappropriate.

- Demonstrate proficiency in urine collections by successfully completing five consecutive error-free mock collections that include: one uneventful scenario, one insufficient specimen quantity scenario, one temperature out of range scenario, one scenario in which the donor refuses to sign the Federal CCF and one scenario in which the donor refuses to initial the specimen bottle tamper-evident bottle seal.
 - The qualified trainer for collectors must monitor and evaluate the individual being trained, in person or by a means that provides real-time observation and interaction between the trainer and the trainee, and the trainer must attest in writing 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.
- Document their completed training as a collector in accordance with the above requirements 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 their name and their employer's name, address, and telephone number. The collector is required to provide their 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 their driver's license with an address.

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

- Be knowledgeable about the direct observed collection procedure as described in the Mandatory Guidelines.
- Be knowledgeable about 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:
 - All steps necessary to perform a direct observed collection.
 - The observer's responsibility for maintaining the integrity of the collection process.
 - Ensuring the security of the specimen throughout the collection process by maintaining visual contact with the collection container until it is delivered to the collector.
 - Ensuring the privacy of the donor being tested.
 - Ensuring that the observation is done in a professional manner, to minimize the discomfort to the donor.

- Avoiding conduct or statements that can be viewed or interpreted as offensive or inappropriate.
- Be the same gender as the donor's gender, as determined by the donor's gender identity. **There are no exceptions to this requirement. Note:** The donor's gender identity may be the same as or different from the donor's sex assigned at birth.
- 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 urine drug test collections for a period of 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).
- Complete 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 their training and provide it to a federal agency upon request.

Before a collector is permitted to collect a specimen for a federal agency, the agency must:

- Ensure that the collector has satisfied the collector requirements described in the Mandatory Guidelines.
- Ensure that the collector, who may be self-employed or an organization (e.g., third party administrator that provides a collection service, collector training organization, federal agency that employs its own collectors) maintains a copy of the collector's training documentation.
- Provide the collector with the name and telephone number of the federal agency's designated representative.

Chapter 2. Collector/Collection Site Records

The collector must maintain their original collector training records (i.e., for initial and refresher training) and provide copies to their employer and, as requested, to the federal agency.

Collection site records must be stored at a secure site designated by the collector or the collector's employer for a minimum of two years. Collection site records includes the collector copies of the OMB-approved Federal CCF for each specimen. Both hardcopy and electronic collection records must be stored and disposed of in a manner that ensures donor confidentiality is maintained. The collection site may convert hardcopy records to electronic records for storage and discard the hardcopy records after 6 months.

Chapter 3. The Collection Site

A collection site may be a permanent or temporary facility, located either at the work site or at a remote site, 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 investigation) and there is no agency-designated site available, a public restroom may be used for the collection using the procedures for a monitored collection (see Chapter 7, Section E). The site must have all necessary personnel, supplies, equipment, facilities, and supervision to provide for specimen collection, security, and temporary storage until the specimen is transferred to an HHS-certified IITF or laboratory, 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 to ensure donor privacy during the collection. Only authorized personnel and the donor may be present in the restricted access area where the collection takes place. The collector must give the donor visual privacy while providing the 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 handling the specimens and completing the paperwork:
 - 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. The ability to:

- Restrict access to the site during the collection where only authorized personnel may be present during the collection.
- Restrict access to collection supplies before, during, and after collection,
- Store collection site records securely, and
- Restrict the 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 based on the projected number of donor specimens collected per year (up to a maximum of 400 blind samples). Every effort should be made to ensure that blind samples are 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:

- Drug positive and negative samples must be validated by the supplier as to their content using the appropriate initial and confirmatory drug tests,
- The supplier must provide information on the blind samples' content, validation, expected results, and stability to the collection site/collector sending the blind sample to the laboratory or IITF and must provide the information upon request, to the MRO, the federal agency for which the blind sample was submitted, or the HHS Secretary.
- Drug positive blind samples must be fortified with one or more of the drugs or metabolites listed in the Mandatory Guidelines, and the concentration should be 1.5 to 2 times the initial drug test cutoff concentration.
- Drug negative blind samples (i.e., certified to contain no drugs) must be validated by the supplier as negative using the appropriate initial and confirmatory tests.
- Substituted or adulterated blind samples must be validated by the supplier using appropriate initial and confirmatory specimen validity tests, and must be shown to meet substitution or adulteration criteria specified in the Mandatory Guidelines at the time of validation.

Each blind sample must be submitted as a split specimen (specimens A and B) with a current Federal CCF that an HHS-certified laboratory or IITF uses for donor specimens.

- The collector provides the required information to ensure that the Federal CCF has been properly completed and provides a fictitious employee identification number or Social Security Number in Step 1c of the Federal CCF and writes fictitious donor initials on the A and B specimen bottle labels/seals.
- 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 a paper 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 (e.g., the content and concentration of the blind samples) to the MRO, to enable the MRO to interpret the results and report them to the agency. The MRO will contact the supplier and/or collector as needed when investigating discrepant results.

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

Federal agencies are required to use the Office of Management and Budget (OMB)-approved Federal CCF when collecting 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).

2017 Federal CCF OMB approved the use of the 2017 Federal CCF as of August 8, 2017. The 2017 Federal CCF may be used as a paper (hardcopy) or electronic (digital) form, or in a combination electronic and paper format.

A proof of the 2017 Federal CCF and guidance for its use are on the SAMHSA website: <https://www.samhsa.gov/workplace>.

2014 Federal CCF OMB extended the use of the 2014 Federal CCF until June 30, 2018. The 2014 Federal CCF may be used as a paper (hardcopy) or electronic (digital) form, or in a combination electronic and paper format.

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

The use of a non-federal CCF or an expired Federal CCF for a federal agency specimen does not, in and of itself, constitute a reason for the test facility to reject the specimen for testing or for the MRO to cancel the test. For example, in rare cases, a collector may use a non-federal CCF or expired Federal CCF for a federal agency collection by mistake or as the only means to conduct a collection under unusual circumstances (e.g., accident investigation test with insufficient time to obtain a OMB-approved Federal CCF). The collector must document that it is a federal agency specimen collection and provide the reason that the incorrect form was used.

In such cases, the test facility processes and tests the specimen, but holds the report pending receipt of a memorandum for the record (MFR) from the collector stating the reason why the incorrect Federal CCF was used for the federal agency collection. The form used and the collector MFR should provide all information required on the Federal CCF.

- If the collector realizes a non-federal CCF or expired Federal CCF was used, they must send an MFR with the specimen stating the reason for use of the incorrect Federal CCF.
- If an IITF or laboratory discovers the use of a non-federal or expired Federal CCF, the collector is notified to provide an MFR with the reason for using the incorrect form. If the collector does not provide an MFR after five business days, the IITF or laboratory will report a rejected for testing result to the MRO, who will cancel the test.
- If an MRO discovers the use of a non-federal or incorrect federal form, the collector is notified to provide an MFR with the reason for using the incorrect form. If the collector does not provide an MFR after five business days, the MRO will cancel the test.

A. Use of an Electronic and Combination Electronic and Paper Federal CCF

A federal agency may use the Federal CCF as an electronic or combination electronic and paper document in its federal workplace drug testing program. These must be the functional equivalent of a paper Federal CCF with respect to integrity, accuracy, and accessibility.

SAMHSA maintains the list of certified laboratories approved to use an ECCF on the SAMHSA website: <https://www.samhsa.gov/workplace>.

“Personally identifiable information” (PII) is information that can be used to distinguish or trace an individual’s identity alone or when combined with other personal identifying information which is linked or linkable to a specific individual. PII that may be on the Federal CCF includes the donor’s Social Security Number (SSN), name, date of birth, telephone numbers, and employment status. All federally regulated employers and drug testing service providers (e.g., collectors, test facilities, MROs, third party electronic CCF providers) must implement procedures and administrative, technical, and physical controls to ensure donor privacy by restricting access to PII and to drug test results on hardcopy and electronic Federal CCFs, and entered into a computer system or database. Access to donor PII and drug test results must be limited to those individuals requiring access to fulfill job duties. Such individuals must receive training to make them aware of their responsibilities for protecting the information. The confidentiality must be maintained from the time the donor PII is obtained through transmission/transport of the Federal CCF, specimen testing, and records handling (i.e., storage, retrieval, and final destruction).

Federally regulated employers and drug testing service providers (e.g., collectors, test facilities, MROs) who use electronic CCFs or combination electronic and paper Federal CCFs must implement procedures and administrative, technical, and physical controls to ensure the authenticity, integrity, and confidentiality of electronic records, and to ensure that electronic signatures are the legally binding equivalent of traditional handwritten signatures. These procedures and controls include, but are not limited to:

- System validation
- The ability to generate accurate and complete copies of records in both human readable and electronic form suitable for inspection, review, and copying upon request of authorized parties (e.g., the MRO, federal agency, or SAMHSA)
- Protection of records to enable accurate and ready retrieval throughout the records retention period
- Limiting system access to authorized individuals (e.g., trained collectors). Procedures must be in place for managing the user authentication system (e.g., assignment, review, revocation).
- Secure, computer-generated, time-stamped audit trails to independently record the date and time of operator entries and actions that create, modify, or delete records from the time of initiation of the Federal CCF (changes should be evident when reviewing the original record, and any electronic or paper copy of the original record)
- Use of authority checks to ensure that only authorized individuals can use the system, electronically sign a record, access the operation or computer system input or output device, alter a record, or perform the operation at hand.

Before implementing an electronic CCF or combination electronic and paper Federal CCF, HHS-certified IITFs and laboratories must provide a detailed plan and proposed standard operating procedures (SOPs) which include the above items for SAMHSA review and approval (i.e., through SAMHSA's National Laboratory Certification Program, NLCP), and must undergo an onsite inspection. The review of validation records, specimen records, SOPs, staff training records, and practices associated with the electronic CCF or combination electronic and paper Federal CCF will be part of the NLCP inspection process. **SAMHSA maintains the list of certified laboratories approved to use an ECCF on the SAMHSA website.**

B. Federal CCF Content Requirements

Test Facility Identification

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 IITF or laboratory to which the specimen will be shipped,
- A corporate name and telephone number (the collector will annotate the address of the IITF or laboratory within the corporation to which the specimen will be shipped, or the test facility that receives the specimen for testing will annotate its address).

Bottle Labels/Seals

The tamper-evident specimen bottle labels/seals may be at the bottom of Copy 1 or may be separate from the form:

- 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 specimen identification number that is 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 the label/seal after it is placed on the specimen bottle.

Required Statements

Wording of required statements must be identical to that on the OMB-approved Federal CCF. The statements must be provided as follows:

- **Instructions for Completing the Federal Drug Testing Custody and Control Form for Urine Specimen Collection**
 - Paper Federal CCF: printed on the back of the donor copy (Copy 5)
 - Electronic CCF or Combination Electronic and Paper Federal CCF: provided to the donor as a separate page (e.g., hardcopy, onscreen, posted at the collection site).
- **Public Burden Statement**
 - Paper Federal CCF: printed on the back of each copy (i.e., Copies 1 through 5).
 - Electronic CCF or Combination Electronic and Paper Federal CCF: provided to

CCF recipients as a separate page (e.g., with the electronically transmitted Federal CCF copies). The Public Burden Statement may be displayed onscreen or posted at the collection site for the donor and collector, and/or provided to the donor as a hardcopy.

- **Privacy Act Statement** (For Federal Employees Only)
 - Paper Federal CCF: printed on the back of the donor copy (Copy 5).
 - Electronic CCF or Combination Electronic and Paper Federal CCF: provided to the donor as a separate page (e.g., hardcopy, onscreen, posted at the collection site).

C. 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.
- The collection site and collector information.
- The testing authority box indicating under which federal agency the specimen is being collected.
- The appropriate box indicating the reason for the test.
- The appropriate box for the drug tests to be performed. If the test is to be performed for a drug other than those listed on the Federal CCF, the “Other” box is marked and the specific drug is annotated.
- The collector enters the donor’s identification [e.g., social security number (SSN) or employee I.D. number] after the collector verifies the donor’s identity. If the donor refuses to provide their SSN or I.D. number, the collector enters a remark in Step 2 on Copy 1.

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. If temperature was outside the acceptable range, the collector enters a remark in Step 2 and takes action as required.
- 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). The collector asks

the donor to write the donor's gender on the Remarks line in Step 2 and initial it. The collector writes the name and gender of the observer and the reason for an observed collection on the Remarks line in Step 2. Note: If there is insufficient room on the Remarks line, the collector may provide a separate MFR explaining the use of an observed collection. The collector must send the MFR to the test facility.

Step 3. To be performed by the collector after the donor has watched the collector pour the specimen from the collection container into the specimen bottles and cap the bottles. This step instructs the collector to:

- Place the labels/seals on the primary and split specimen bottles as the donor watches,
- 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.
 - Record the following:
 - Their 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.

Note: For electronic CCFs or combination electronic and paper CCFs, if the donor refuses to sign electronically but is willing to sign a paper CCF with a wet signature, the collector must print the ECCF, Copies 1-5. The donor must sign in Step 5 of Copies 2-5 using a wet signature and the collector must sign in Step 4 of Copies 1-5 using a wet signature.

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 HHS-certified IITF or laboratory in accordance with federal requirements.
- Include the collector's printed 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 HHS-certified IITF or laboratory.

Note: 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 subsequent Steps are made at the HHS-certified IITF or laboratory.

- Place the sealed specimen bottles in a leak-resistant container including the absorbent material.
- For Paper CCFs and Combination Electronic and Paper CCFs: Place the Test Facility copy (Copy 1) in the package with the specimen (i.e., in a compartment separate from the specimen bottles).
 - For Combination Electronic and Paper CCFs: Copy 1 sent with the specimen must be either the single authoritative copy, or a reprint of Copy 1 that has been signed by the collector using a wet signature.
- For Electronic CCFs: The collector must either:
 - Include a printed copy of the Test Facility copy (Copy 1) with the specimen; or
 - Apply a label to the outside of the specimen package, with the specimen identification number, test facility name and contact information, and collection site name and contact information.
- Seal and prepare the specimen package for shipment, and distribute the remaining CCF copies as required.

D. Federal CCF Distribution

Paper CCFs and Combination Electronic and Paper Federal CCFs

- Copy 1 (Test Facility Copy) signed by the collector is shipped with the specimen package to the HHS-certified IITF or laboratory.
- Copy 2 (MRO Copy) signed by the donor is sent to the MRO

- For Paper CCFs:
 - Original Copy 2 is sent by courier or mail, or
 - A copy of Copy 2 is sent via fax or provided electronically. The collector maintains the original Copy 2 in the collection site records.
- Copy 3 (Collector Copy) is maintained in the collection site records.
- Copy 4 (Employer Copy) is sent via fax, courier, or mail, or is provided electronically.
- Copy 5 (Donor Copy) is provided to the donor. This may be a printed copy or a copy that is electronically provided.

Note: Copies 2 through 5 are identical.

Electronic Federal CCF

- Copy 1 (Test Facility Copy) signed by the collector is electronically provided to the HHS-certified IITF or laboratory.
- Copies 2 through 5 are signed by the donor:
 - Copy 2 is provided electronically to the MRO.
 - Copy 3 is maintained in the collection site records.
 - Copy 4 is provided electronically to the employer.
 - Copy 5 is provided to the donor. This may be a printed copy or a copy that is electronically provided.

Note: Copies 2 through 5 are identical.

Employers, collectors, test facilities, and MROs who send or receive CCFs electronically are responsible for ensuring the security of data transmissions and limiting access to any data transmission, storage, and retrieval systems.

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 an alternative photo identification issued by a federal, state, or local government agency), or

- Positive identification by the supervisor of the donor or by a federal agency representative.

If the identity of the donor cannot be established, the collector must not proceed with 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 have a restricted access area 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 as a restricted access area during the time a specimen is collected.

A collector must:

- Prohibit unauthorized personnel from entering the collection site during the collection;
- Ensure the privacy of the donor;
- Perform only one donor collection at a time;
- Restrict access to collection supplies before, during and after 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, storage, and transport procedures,
- Ensure that the Federal CCF is completed and distributed as required (e.g., paper Copy 1 packaged with the specimen and sealed for shipment; electronic Copy 1 provided electronically) 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 composition of drugs and/or metabolites in the urine 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 composition of drugs and/or metabolites in the urine 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),
 - 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, and
 - Sufficiently transparent to enable an objective assessment of the urine specimen appearance and identification of abnormal physical characteristics without opening the bottle.
3. **Thermometer.** The thermometer must be capable of temperature readings between 90°-100°F (32°-38°C). The thermometer must accurately measure the temperature of the specimen and not contaminate the specimen. The thermometer may be affixed to or built into the collection container as supplied or placed on the collection container after the donor gives the collection container with the specimen to the collector. Alternately, the collector

may use another technology to measure the specimen temperature (e.g. thermal radiation scanning), providing the thermometer does not come into contact with the specimen.

4. **Federal CCFs.** An OMB-approved Federal CCF as described in Chapter 5.
 5. **Tamper-evident labels/seals.** Two tamper-evident labels/seals are used to seal the specimen bottles (i.e., primary and split specimens). Occasionally, a tamper-evident label/seal 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. **Specimen package.** The sealed, tamper-resistant container (e.g., plastic bag) which contains the specimen bottle(s) and Federal CCF from a urine drug test collection. If an electronic Federal CCF was used, the collector must either 1) include a printed copy of the Federal CCF (for informational purposes only) in the specimen package or 2) apply a label to the outside of the specimen package with the specimen identification number, test facility name and contact information, and collection site name and contact information.
 7. **Leak-resistant container.** A container (e.g., plastic bag) that is leak-resistant and large enough to hold two specimen bottles.
 8. **Absorbent material.** The absorbent material is placed inside the leak-resistant container 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.
 9. **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/mailler if a courier hand-delivers the specimen package containing the specimen bottles directly from the collection site to the IITF or laboratory.
 10. **Bluing agent.** Bluing agent is added to the toilet bowl and water tank to prevent undetected specimen dilution by the donor.
 11. **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 specimen package containing the specimen bottles 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 period of time. These conditions may affect the test results of a urine specimen.**
12. **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).

13. **Paper Federal CCFs. All collection sites, including those using electronic and combination electronic and paper Federal CCFs, should maintain a supply of paper Federal CCFs.**

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.
 - You must provide a means for the donor to wash their hands before and after the collection. You must secure the water source after the donor washes their 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, you must perform a monitored collection as described in Chapter 7, Section E.
 - 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 fails to arrive at the collection site at the assigned time for the drug test, you must follow the federal agency policy or 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 they are unable to urinate. **If the donor states that they are unable to provide a urine specimen, continue with the collection procedure through Step 11 below.**
4. Verify the donor's identity with a photo identification (see Chapter 6). If the donor requests, you must provide identification (e.g. employee badge, employee list).
5. Describe the basic collection procedure to the donor and inform the donor that the instructions for completing the Federal Custody and Control Form are located on the back of the Federal CCF or are available upon request.
6. Answer any reasonable and appropriate questions that the donor has about the collection process.

7. Complete Step 1 of the Federal CCF (See Chapter 5).

- Ensure that the specimen identification number on the Federal CCF matches the identification number printed on the specimen bottle labels/seals and on the specimen package label (if any).
- Verify any collection demographic information in Step 1 of the Federal CCF.
- 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.) that could be used to conceal items or substances that could be used to adulterate or substitute the urine specimen.
 - Do not ask the donor 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 you suspect 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 their 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 their pockets and display the items to ensure that no items are present that could be used to adulterate, substitute or dilute 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 present that appears to have been brought to the collection site with the intent to adulterate, substitute or dilute the specimen, this is considered a refusal to test. You must stop the collection and report the refusal to test to the federal agency to ensure immediate notification is received (see Chapter 8, Section B). Note: Document the item found in an MFR (e.g., photograph, written description).
 - If an item that could be used to adulterate, substitute or dilute 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. Note: Document the item found in an MFR (e.g., photograph, written description). Return the item(s) to the donor at the end of the collection.
 - If the donor refuses to display the items in their pockets, this is considered a refusal to test. You must stop the collection and report the refusal to test immediately to the federal agency (see Chapter 8, Section B).
9. Instruct the donor to wash and dry their hands under your observation prior to the urine collection.
- Liquid soap is preferred over bar soap, because bar soap gives the donor the opportunity to conceal soap shavings under their fingernails in an attempt to adulterate the specimen.
 - After washing their hands, the donor must remain in your 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.
 - If the donor refuses to wash their hands when instructed, this is considered a refusal to test. You must stop the collection and report the refusal to test to the federal agency.
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 in view of the donor. 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 they are 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, they have demonstrated the inability to provide a specimen. Follow the Insufficient Specimen procedure in Chapter 7, Section F.

12. Direct the donor to:

- Provide the specimen in the privacy of the restroom/stall/partitioned area 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 they have 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: You must note any unusual behavior or appearance of the donor on the Federal CCF. If you detect any conduct that clearly indicates an attempt to tamper with a specimen, you must report a refusal to test immediately to the federal agency.

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

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

13. After you receive the specimen from the donor, read the temperature.

- 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.” You will perform a second, direct observed collection, and send both specimens to an HHS-certified laboratory (not an IITF) for testing. (See exception in first Note below.)
 - Record an appropriate comment on the Remarks line in Step 2 of the Federal CCF for the first specimen to identify this as the first of two specimens collected and the reason why two specimens were collected.
 - Complete the first collection before initiating the second collection, including Step 14 (examining the physical characteristics of the urine).
 - 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 specimen to indicate why two specimens were collected, including a cross reference to the specimen identification number of the first specimen.

Note: The specimen with unacceptable temperature and its Federal CCF are sent to an HHS-certified laboratory regardless of the specimen volume. Exception: If the unacceptable temperature is due to a measurement problem (e.g., no reading due to extremely low volume, temperature strip failure) discard the urine collected and immediately begin a second collection using the same Federal CCF and the same procedures (not directly observed). Use a new collection container for the second collection.

Note: If the donor provides less than 45 mL for the second specimen, follow the Insufficient Specimen procedures in Chapter 7, Section F. Discard the second specimen in accordance with Step 2 of this section, as applicable. Do not send the second specimen for testing if the volume is less than 45 mL (see Appendix B).

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). Discard any urine, document the refusal to test on the Federal CCF and send all copies of the Federal CCF to the federal agency’s designated representative.

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).
- If there are no abnormal characteristics indicative of adulteration or substitution by the donor, proceed with the collection procedure. Go to Step 15.
- If you observe any abnormal characteristic(s) that appear to be due to adulteration or substitution by the donor, you will perform a second, direct observed collection and send both specimens to an HHS-certified laboratory (not an IITF) for testing:
 - Record an appropriate comment on the Remarks line in Step 2 of the Federal CCF for the first specimen to identify this as the first of two specimens collected and the reason why two specimens were collected.
 - Complete the first collection before initiating the second collection by continuing with the procedure in Step 15.
 - Begin the 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 the Federal CCF for the second specimen to indicate why two specimens were collected, including a cross reference to the specimen identification number of the first specimen.

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

Note: If the donor provides less than 45 mL for the second specimen, follow the Insufficient Specimen procedures in Chapter 7, Section F. Discard the second specimen in accordance with Step 2 of this section, as applicable. Do not send the second specimen for testing if the volume is less than 45 mL (see Appendix B).

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). Discard any urine, document the refusal to test on the Federal CCF and send all copies of the Federal CCF to the federal agency's designated representative.

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.
 - If 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 Specimen 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. Record the reason for not collecting a urine specimen on the Federal CCF, and notify the federal agency's designated representative for authorization of an alternate specimen to be collected. The federal agency may choose to provide the collection site with a standard protocol to follow in lieu of requiring the collector to notify the agency's designated representative for authorization in each case. You must send the appropriate copies of the Federal CCF to the MRO and to the federal agency's designated representative (see Insufficient Specimen procedure in Chapter 7, Section F).
 - If an alternate specimen is authorized, the collector may begin the collection procedure for the alternate specimen in accordance with the Mandatory Guidelines. If the donor refuses to provide an alternate specimen, the collector stops the collection and reports the refusal to test (see Chapter 8, Section B).

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 two specimen bottles labeled "A" and "B".

- Pour at least 30 mL into the "A" Bottle and at least 15 mL into the "B" bottle.
- Secure the lid/cap on each 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 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 (i.e., printed with the same specimen identification number as the Federal CCF) to the bottle, and
 - Apply a second, separate tamper-evident seal to seal the specimen bottle.

- Place the additional seal perpendicular to the original label/seal, to avoid obscuring information on the original 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.

Note: If the donor refuses to initial the second seal, the collector should note this on the Remarks line in Step 2 and continue with the collection process. This is not considered a refusal to test.

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 them to continue observing the collection procedure after the bottles have been sealed, and that they are allowed to wash their 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 their date of birth,
 - Provide their printed name,
 - Provide day and evening contact telephone numbers.

Note: For electronic CCFs or combination electronic and paper CCFs, some of the items above (i.e., date of birth, printed name and telephone numbers) may already have been entered.

- 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. **Note:** This does not constitute a refusal to test.

Note: For electronic CCFs or combination electronic and paper CCFs, if the donor refuses to sign electronically but is willing to sign a paper CCF with a wet signature, the collector must print the ECCF, Copies 1-5. The donor must sign in Step 5 of Copies 2-5 using a wet signature and the collector must sign in Step 4 of Copies 1-5 using a wet signature.

24. Complete the collector chain of custody portion in Step 4 on Copy 1 of the Federal CCF:

- Provide the collector's printed 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. Prepare specimen package.

Place the sealed specimen bottles in a leak-resistant container including the absorbent material.

Paper CCFs and Combination Electronic and Paper CCFs:

- Place the Test Facility copy (Copy 1) in the package with the specimen (i.e., in a compartment separate from the specimen bottles). Note: Attach any collector MFRs for the specimen to Copy 1 prior to sealing in the compartment.
 - For Combination Electronic and Paper CCFs: Copy 1 sent with the specimen must be either the single authoritative copy, or a reprint of Copy 1 that has been signed by the collector using a wet signature.

Electronic Federal CCF: The collector must either:

- Include a printed copy of the Test Facility copy (Copy 1) with the specimen; or
- Apply a label to the outside of the specimen package, with the specimen identification number, test facility name and contact information, and collection site name and contact information.

Seal and prepare the specimen package for shipment, and distribute the remaining CCF copies as required.

26. Give a copy of the Federal CCF to the donor. This may be a printed copy or a copy provided electronically after the collection. Remind the donor that they may list any

prescription and over-the-counter medications on a separate sheet or on the back of the donor's copy of the Federal CCF. This information may help the donor to remember what medications they may have taken if they are 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 they may leave the collection site.
28. Prepare the sealed specimen package containing the specimen bottles for transport to the IITF or laboratory within 24 hours or during the next business day.
 - Place the sealed specimen package(s) to be shipped into a shipping container (e.g., box, express carrier mailer). Several specimen packages 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 packages in a manner that protects the specimens from damage.
 - If the tamper-evident label/seal 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 the Federal CCF to the MRO (Copy 2) and to the agency's designated representative (Copy 4) **within 24 hours after the collection or during the next business day.**
 - The Federal CCF distribution process must be coordinated between the collection site and the MRO to ensure that procedures meet the MRO's or federal agency's requirements. Acceptable transmission methods include, but are not limited to:
 - 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 MRO or the collection site must maintain the original Copy 2 with the donor's signature (i.e., paper Copy 2 with the donor's handwritten wet-ink signature or electronic Copy 2 with the donor's electronic signature) for the record retention period specified by the federal agency.
30. Submit the specimen to the HHS-certified 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 specimen package 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).

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 explain to the donor why a direct observed collection is being conducted. If the donor declines to allow a direct observed collection 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 (see Appendix A). The observer's gender must be the same as the donor's gender, which is determined by the donor's gender identity. **There are no exceptions to this requirement.** The donor's gender identity may be the same as or different from the donor's sex assigned at birth. At the point in a routine collection where the donor enters the restroom with the collection container (see Chapter 7, Section C, Step 12), a direct observed collection includes the following additional steps:

1. The collector informs the donor that the gender of the observer will match the donor's gender, which is determined by the donor's gender identity.
 - The collector asks the donor to identify the donor's gender on the Remarks line in Step 2 of the Federal CCF and initial it.
 - The donor is provided an observer whose gender matches the donor's gender.

- The collector documents the observer's name and gender on the Remarks line in Step 2 of the Federal CCF.
 - If there is no collector of the same gender as the donor's gender identity, the collector or collection site supervisor must select another individual trained in direct observed specimen collections. The individual must meet the HHS Mandatory Guidelines qualifications for an observer (see Chapter 1).
2. The observer enters the restroom with the donor.
 3. 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).
 4. 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.
 5. The observer must maintain visual contact with the collection container until the donor hands the container to the collector
 6. 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, or if the same individual serves as both observer and collector, the collector may receive the collection container from the donor while they are both in the restroom.
 7. 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 send a separate explanatory MFR.
 8. The collector continues with the routine collection procedures (see Chapter 7, 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 a monitor accompanies the donor into the restroom to check 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 Chapter 7, 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 remains in the restroom, but outside the stall, while the donor is providing the specimen.
 - The monitor must be the same gender as the donor's gender identity, 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 may be an individual other than the collector and is not required to be a trained collector.
2. The monitor listens for signs of tampering with the specimen. The monitor must not watch the donor urinate into the specimen container.
3. 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).
4. 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.
5. 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, and
 - The monitor must ensure that the employee takes the collection container directly to the collector as soon as the employee has exited the enclosure, or
 - If the same individual serves as both monitor and collector, the collector may receive the collection container from the donor while they are both in the restroom.
6. The collector provides the name of the monitor (if applicable) on the Remarks line in Step 2 on Copy 1 of the Federal CCF.
7. The collector continues with the routine collection procedures (see Chapter 7, Section C, Step 13).

F. Insufficient Specimen

If a donor tells the collector that they cannot provide a specimen, the collector must begin the collection procedure regardless of the reason given. The donor must demonstrate their inability to provide a valid specimen when they come out of the restroom with an empty collection container. Immediately begin a second collection using the same procedures, the same collection container (i.e., if no specimen was provided upon the first attempt), and the same Federal CCF.

1. If the donor indicates that they 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 they are 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 in Step 2 of the Federal 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 they are 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 for authorization to collect an alternate specimen. The federal agency may provide the collection site with a standard protocol to follow instead of requiring the collector to notify the agency's designated representative for authorization in each case. If an alternate specimen is authorized by the federal agency, begin the alternate specimen collection procedure.
 - Discard the urine collected (if any).
 - Provide a copy of the Federal CCF (as described in Step 26 of the Collection Procedure in Chapter 7, Section C above) to the donor and request that the donor leave the collection site.
 - Discard Copy 1 of the Federal CCF (no valid specimen was collected).
 - Provide a copy of the Federal CCF to the MRO and to the federal agency's designated representative within 24 hours or the next business day (as described in Step 29 of the Collection Procedure in Chapter 7, Section C above).
3. If the donor refuses to attempt to provide a specimen, refuses to provide a second specimen, leaves the collection site before the collection process is completed, refuses a direct observed collection, or refuses to provide an alternate specimen, these are

considered 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. You must note any unusual behavior or appearance of the donor on the Federal CCF.
2. If you detect any conduct that clearly indicates an attempt to tamper with a specimen (e.g., substitute urine in plain view or an attempt to bring into the collection site an adulterant or urine substitute), you must report a refusal to test immediately to the federal agency. See additional information in Section B below.
3. If the donor's actions indicate an attempt to substitute or adulterate a specimen and the donor has already provided a specimen, you will complete the collection procedure for the first specimen; perform a second, direct observed collection; and send both specimens to an HHS-certified laboratory (not to an IITF) for testing.
 - Record an appropriate comment on the Remarks line in Step 2 of the Federal CCF for the first specimen to identify this as the first of two specimens collected and the reason why two specimens were collected.
 - Complete the first collection using the procedures in Chapter 7, Section C, before initiating the second collection.
 - Begin the 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 the Federal CCF for the second specimen 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: 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 Section B below). Discard any urine, document the refusal to test on the Federal CCF and send all copies of the Federal CCF to the federal agency's designated representative.

4. If the donor fails to arrive at the assigned time within a reasonable time, as determined by the federal agency:

- Contact the federal agency's designated representative to obtain guidance on the action to be taken.
- This is considered a refusal to test (except for a pre-employment 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 their pockets at the beginning of the collection, disrupts the collection process, or refuses to wash their 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 their first specimen has insufficient volume,
5. The donor fails or declines to participate in an alternate specimen collection (e.g., oral fluid) as directed by the federal agency or collector,
6. The donor leaves the collection site before completion of the collection. Exception for pre-employment tests: if the donor for a pre-employment test leaves the collection site before the collector provides or before the donor selects a specimen collection container, this is not considered a refusal to test. (See Chapter 7, Section 7, Collection Procedure, Step 10.) If the donor for a pre-employment test leaves after that step, before the collection is complete, the collector reports a refusal to test.
7. The donor possesses or wears a prosthetic or other device that could interfere with the drug test,
8. The donor brings materials to the collection site with the intent to adulterate, substitute or dilute their specimen or conduct clearly indicates an attempt to adulterate, substitute, or dilute the specimen.
9. The donor admits to the collector that they have adulterated or substituted their specimen.

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

1. Notify the agency's designated representative by a means (e.g., telephone, secure fax, 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 of the Federal CCF, discards any urine, 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, legal document and will be part of the litigation package if a specimen comes under legal challenge.

Paper Federal CCF

The collector should **never** use correction fluid on the Federal CCF, and should never overwrite or obscure 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, they should:

1. Make a line through the erroneous information, leaving the original information legible,
2. Write the correct information near (e.g., beside or above) 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, address 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., accident investigation) or when Federal CCFs at the collection site have outdated information.

Electronic CCF and Combination Electronic and Paper Federal CCF

An electronic CCF or combination electronic and paper Federal CCF must have a secure, computer-generated, time-stamped audit trail to independently record the date and time of operator entries and actions that create, modify, or delete information from the time of initiation of the Federal CCF (changes should be evident when reviewing the original record, and any electronic or paper copy of the original record).

Collection sites must maintain a supply of paper Federal CCFs. A paper Federal CCF may be used in the event of a software/hardware problem preventing collections using an electronic CCF or combination electronic and paper Federal CCF. In addition, collection sites should have the ability to print the electronic Federal CCF on demand. This capability would allow the collector to print the Federal CCF in the event of a problem preventing completion of a collection using an electronic CCF (e.g., allowing for handwritten collector and donor signatures in the event of a problem with the electronic signature system).

There are three categories of collector errors:

1. Fatal flaws that result in an HHS-certified IITF or laboratory rejecting a specimen or an MRO cancelling a test,

2. Correctable flaws that result in an HHS-certified 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 HHS-certified IITF or laboratory or cancellation by the MRO.

The collector should not access the Federal CCF or the specimen bottles after the package has been sealed in the presence of the donor. If the collector realizes they have made a correctable flaw or omission after the Federal CCF or CCF copy has been sealed in the specimen package, the collector should proactively send an explanatory MFR to the HHS-certified IITF or laboratory.

The collector must take **immediate** steps to provide an MFR to the HHS-certified 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/collection errors).

Appendix A: Direct Observed Collection Procedure

General Note:

For observed collections decided at the collection site - collector contacts a collection site supervisor for concurrence and explains to the donor why a direct observed collection is being conducted. If the donor declines to allow a direct observed collection, it is considered a refusal to test (see Chapter 8, Section B).

1

Collector informs the donor that the gender of the observer will match the donor's gender (determined by the donor's gender identity).

- Collector asks the donor to identify the donor's gender on the Remarks line in Step 2 of the Federal CCF and initial it.
- Donor is provided an observer (gender matches the donor's gender).
- Collector documents the observer's name and gender on the Remarks line in Step 2 of the Federal CCF.



If there is no collector of the same gender as the donor to serve as the observer, the collector or collection site supervisor selects another individual trained in direct observed specimen collections.

2

Observer enters the restroom with the donor.

- Observer must directly watch the urine go from the donor's body into the collection container.

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).



- Observer must never touch or handle the collection container unless the observer is also the collector.
- Observer must maintain visual contact with the collection container until the donor hands the container to the collector

3

After the donor has completed urinating into the collection container:

- Donor and observer leave the restroom and the donor hands the collection container directly to the collector **OR**
- If the same individual serves as both observer and collector, the collector may receive the collection container from the donor while they are both in the restroom.



4

Collector checks the box for an observed collection in Step 2 of the Federal CCF.

- Collector provides the reason for an observed collection on the Remarks line in Step 2 of the Federal CCF.
- Collector continues with the routine collection procedures (see Chapter 7, Section C, Step 13).



Appendix B: Two Specimens from the Same Collection Event

