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

Collection Site Manual

For the
Collection of Urine Specimens 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).

Disclaimer

The Department of Health and Human Services (HHS) recommends that each federal agency use the information contained in this collection site manual to ensure consistency and to improve the overall quality of the review process. This collection site manual is for informational purposes only and can be modified to reflect the Federal Agency's Drug-Free Workplace Policy.

If there are questions regarding this manual, please contact Division of Workplace Programs staff at 240.276.2600 or see https://www.samhsa.gov/workplace

Table of Contents

References

(available at https://www.samhsa.gov/workplace**)**

1. Federal Custody and Control Form (Federal CCF)

2. HHS Urine Specimen Collection Handbook (HHS Collection Handbook)

3. *Mandatory Guidelines for Federal Workplace Drug Testing Programs* (HHS Mandatory Guidelines). Published January 23, 2017 (82 FR 7920), effective October 1, 2017.

Introduction

The Substance Abuse and Mental Health Services Administration (SAMHSA) within the U.S. Department of Health and Human Services (HHS) establishes the scientific and technical guidelines to be used by U.S. federal agencies, drug testing facilities, and collection sites used for federally regulated workplace drug testing. Federally regulated specimens must be collected in accordance with the *Mandatory Guidelines for Federal Workplace Drug Testing Programs* (HHS Mandatory Guidelines) published on January 23, 2017 (effective October 1, 2017) and must be tested at an HHS-certified laboratory or an HHS-certified Instrumented Initial Test Facility (IITF).

This Collection Site Manual provides explanatory comments and references for each question included in the *Collection Site Checklist for Collection of Urine Specimens for Federal Agency Workplace Drug Testing Programs*. SAMHSA developed the Collection Site Manual for federal agencies' use in evaluating collection sites that provide specimen collection services to the federal agencies, to verify and document compliance with federal requirements.

Federal Custody and Control Form

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 HHS Mandatory Guidelines, the collector begins the chain of custody documentation at the collection site using a Federal CCF.

The Office of Management and Budget (OMB) Federal CCF must be used to document custody and control of each specimen at the collection site. The Federal CCF may be used as a paper (hardcopy) form, an electronic (digital) form, or in a combination electronic and paper format. Before an HHS-certified test facility may use an electronic CCF (ECCF: electronic form or combination electronic/paper form) for regulated specimens, the test facility must be approved to use that ECCF system by SAMHSA, through the National Laboratory Certification Program (NLCP).

OMB approved the use of the 2017 Federal CCF as of August 8, 2017. The Division of Workplace Programs (DWP), Substance Abuse and Mental Health Services Administration (SAMHSA) have released guidance associated with the 2017 Federal CCF. This is posted on the DWP/SAMHSA Drug Testing website at https://www.samhsa.gov/workplace/drug-testing. OMB extended the use of the expired 2014 Federal CCF until June 30, 2018.

The 2014 Federal CCF may be used as a paper (hardcopy) form or electronic (digital) form, or in a combination electronic and paper format during this time period.

As of July 1, **2018**, the 2017 Federal CCF will be the only Federal CCF for regulated specimens. If a regulated specimen is received at a test facility accompanied by the 2014 Federal CCF after June 30, 2018, the test facility (IITF or laboratory) must treat this as a correctable flaw and require a memorandum for the record (MFR) from the

collector, or the specimen may be rejected by the test facility and canceled by the Medical Review Officer (MRO).

Links to both the 2014 and 2017 Federal CCFs are on the SAMHSA website at https://www.samhsa.gov/workplace/resources.

Collection Site Manual Instructions

A federal agency must ensure that collectors and collection sites satisfy all requirements in subparts D, E, F, G and H of the *Mandatory Guidelines for Federal Workplace Drug Testing Programs* (HHS Mandatory Guidelines) published on January 23, 2017 (effective October 1, 2017).

This Collection Site Manual is designed to assist the Drug Program Coordinator or designee and collection site personnel in evaluating collection site performance based on onsite inspections and self-evaluations. A federal agency is responsible for inspecting 5 percent (up to a maximum of 50) collection sites each year, selected randomly from those sites used to collect federal agency specimens. A federal agency must investigate reported collection site deficiencies and take appropriate action, which may include an onsite inspection or collection site self-evaluation using the *Collection Site Checklist for Collection of Urine Specimens for Federal Agency Workplace Drug Testing Programs* and the HHS Urine Specimen Collection Handbook.

Guidance and Information

To use this manual, you will need:

- *Mandatory Guidelines for Federal Workplace Drug Testing Programs* (HHS Mandatory Guidelines) published on January 23, 2017 (effective October 1, 2017)
- HHS Urine Specimen Collection Handbook (HHS Collection Handbook)
- Guidance provided by the federal agency's drug-free workplace program or by HHS relating to regulated specimen collection

Terms and Definitions

Before you can begin using this manual, you need to familiarize yourself with the checklist questions and comments in each section. This can be done by following these easy steps: (1) read each question and the related comments, (2) read the HHS Mandatory Guidelines section(s) referenced for each question, and (3) understand the federal agency policy.

Checklist

Each question in the *Collection Site Checklist for Collection of Urine Specimens for Federal Agency Workplace Drug Testing Programs* is designed to address the requirements in HHS Mandatory Guidelines subparts D, E, F, G and H. The inspector/collection site reviewer answers each question based on these requirements and their review of the collection site standard operating procedures, practice, and records. The individual completing the checklist will:

1. Circle the appropriate **YES** or **NO** answer for each checklist question.
2. If required for a **NO** answer, check the deficient area(s) for the checklist question.
3. Record comments in the space provided to explain the specific reason for each **NO** answer.

Section Evaluation

Each checklist section contains a section evaluation page. The inspector/collection site reviewer uses the section evaluation to summarize and classify the seriousness of identified deficiencies. The individual completing the checklist will:

1. For each checklist question in the section with a **NO** answer, explain the potential problem or identified non-compliance.
2. Mark the overall section evaluation at the top of the page as appropriate:
   - Deficiencies require immediate corrective action by the collection site
   - Deficiencies were identified but do not require immediate correction action
   - No deficiencies were identified.

Collection Site Evaluation Form

The Collection Site Evaluation Form is completed by inspectors (for onsite inspections) and by collection site personnel (for self-evaluations) and is used by the federal agency DPC or designee to determine the inspection outcome.

Inspector/Collection Site Reviewer

1. In the Overall Section Summary, assign a numerical "score" for each checklist section, based on the section evaluation:

   - Record a "0" on the evaluation form for each section summary where serious deficiencies were identified.
   - Record a "1" for each section summary where deficiencies were identified but do not require immediate corrective action.
   - Record a "2" for each section summary where no deficiencies were identified.

2. In the appropriate "Inspector/Collection Site Reviewer" columns under "Overall Summary of Serious Deficiencies," list the sections identified as having serious deficiencies and those with no serious deficiencies.

3. Add the individual section scores to determine the rating and record the total in the "Rating" space for "Inspector/Collection Site Reviewer" under "Inspection Outcome."

4. Sign and date in the appropriate space at the bottom of the form. Inspectors sign the "Onsite Inspection by" line; Collection Site Reviewers sign the "Self-Evaluation by" line.

Federal Agency Reviewer

1. Review the checklist completed by the inspector (for onsite inspections) or by collection site personnel (for self-evaluations).

2. Based on your review, in the appropriate "Federal Agency/Designee" columns under "Overall Summary of Serious Deficiencies," list the sections identified as having serious deficiencies and those with no serious deficiencies.

3. Note (e.g., by circling) any sections with evaluations differing from the inspector/collection site reviewer evaluation. If there are differences, calculate a final rating based on your individual section scores.

4. Record the final rating in the "Rating" space for "Federal Agency/Designee" under "Inspection Outcome."

5. Determine the Inspection Outcome based on the following criteria in each section:

   ____ *Serious deficiencies were identified (0 points)*
   ____ *Deficiencies were identified (1 point)*
   ____ *No deficiencies were identified (2 points)*

   - **Acceptable** = A rating of 5 or greater and no more than 1 section with a serious deficiency identified.

   - **Unacceptable** = A rating less than 5 or more than 1 section with a serious deficiency identified.

6. Additional comments concerning the inspection outcome should be recorded in the space provided.

Definitions

Adulterated Specimen: A specimen that has been altered, as evidenced by test results showing either a substance that is not a normal constituent for that type of specimen or showing an abnormal concentration of an endogenous substance.

Blind Sample: A sample submitted to an HHS-certified test facility for quality assurance purposes, with a fictitious identifier, so that the test facility cannot distinguish it from a donor specimen.

Collection site: The location where specimens are collected.

Collector: A person trained to instruct and assist a donor in providing a specimen.

Chain of Custody Procedures: Procedures that document the integrity of each specimen or aliquot from the point of collection to final disposition.

Chain of Custody Document: A form used to document the control and security of the specimen and all aliquots. The document may account for an individual specimen, aliquot, or batch of specimens/aliquots, and must include the name and signature of each individual who handled the specimen(s) or aliquot(s), and the date and purpose of the handling.

Dilute Specimen: A urine specimen with creatinine and specific gravity values that are lower than expected but are still within the physiologically producible ranges of human urine.

Federal Custody and Control Form (CCF): The Office of Management and Budget (OMB)-approved form that is used to document the collection and the chain of custody of a specimen from the time the specimen is collected until it is received by the testing facility (i.e., HHS-certified laboratory, or for urine, HHS-certified instrumented initial test facility). The form may be a paper (hardcopy), electronic, or combination electronic and paper format (hybrid). The form may also be used to report the test result to the Medical Review Officer (MRO).

Gender Identity: Gender identity means an individual's internal sense of being male or female, which may be different from an individual's sex assigned at birth.

Instrumented Initial Test Facility (IITF): A permanent location where (for urine) initial testing, reporting of results, and recordkeeping are performed under the supervision of a responsible technician.

Laboratory: A permanent location where initial and confirmatory testing, reporting of results, and recordkeeping are performed under the supervision of a responsible person.

Medical Review Officer: A licensed physician who reviews, verifies, and reports a specimen test result to the federal agency.

Oral Fluid Specimen: An oral fluid specimen is collected from the donor's oral cavity and is a combination of physiological fluids produced primarily by the salivary glands.

Rejected for Testing: The result reported by an HHS-certified laboratory or (for urine) HHS-certified IITF when no tests are performed for a specimen because of a fatal flaw or unrecovered correctable error.

Specimen: Fluid or material collected from a donor at the collection site for the purpose of a drug test.

Split Specimen Collection (for Urine): A collection in which the specimen collected is divided into a primary (A) specimen and a split (B) specimen, which are independently sealed in the presence of the donor.

Substituted Specimen: A specimen that has been submitted in place of the donor's urine, as evidenced by creatinine and specific gravity values that are outside the physiologically producible ranges of human urine.

Section A. Collection Site

Collection Site

Question A-1. *Does the collection site have provisions to ensure donor privacy during the specimen collection procedure? (YES/NO)*

Comment: The collection site must have the ability to ensure donor privacy during specimen collections. This may be in the form of an enclosed stall in a multi-stall restroom, a single person restroom, a partitioned area that allows for individual privacy, or a mobile restroom.

Reference: HHS Mandatory Guidelines (subpart E – section 5.2.a; subpart H – section 8.1.c)

Question A-2. *Does the collection site have the following? (YES/NO)*

*If **NO**, check the deficient area(s):*

____ *a. A means for washing hands*

____ *b. A suitable clean surface, inaccessible to the donor, for the collector to use as a work area*

____ *c. A secure temporary storage area for maintaining specimens until they are transferred to an HHS-certified test facility*

Comment: The collection site must have a means for the donor to wash his or her hands prior to and after urination. The work area is used by the collector to handle the specimens and to complete required paperwork (e.g., Federal CCF). The collector work area should be external to the restroom where the collection occurs; however, it may be inside the restroom, if the donor still has privacy while providing the urine specimen. The work area must be clean and not accessible to the donor. The collection site must have an appropriate secure temporary storage area for maintaining specimens until they are transferred to an HHS-certified test facility. The specimen storage area should not be exposed to high temperatures for an extended period of time, as this may affect the test results of a urine specimen.

Reference: HHS Mandatory Guidelines (subpart E – section 5.2.b - c and subpart H - section 8.3.h.5.i) and HHS Collection Handbook

Question A-3. *Does the collection site have procedures or restrictions to prevent the following? (YES/NO)*

*If **NO**, check the deficient area(s):*

____ *a. Unauthorized access to the site during the collection*

____ *b. Unauthorized access to the collection materials/supplies*

____ *c. Unauthorized access to collection site records*

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

Comment: To ensure specimen integrity, the collection site must have procedures or restrictions in place to prevent unauthorized access as described in this question.

Reference: HHS Mandatory Guidelines (subpart E - section 5.2.d-g)

Question A-4*. Does the collection site have the required supplies for federally regulated urine specimen collections? (YES/NO*)

Comment: The collection site must have all the supplies needed to complete a specimen collection such as collection kits (i.e., single-use collection container with a means to measure the urine temperature and two specimen bottles), Federal CCFs, tamper-evident tape/seals, leak-resistant container (e.g., plastic bag) with separate sealable compartments for specimen bottles and CCF, absorbent material, shipping containers, bluing agent, and disposable gloves. Collection kits must include a single-use collection container able to hold at least 55 mL, one specimen bottle able to hold at least 35 mL, and one specimen bottle able to hold at least 20 mL. Collection containers and specimen bottles must not substantially affect the composition of drugs and/or metabolites in the specimen collected.

Reference: HHS Mandatory Guidelines (subpart G – section 7.1 and 7.2) and HHS Collection Handbook

Question A-5. *Is access to collection supplies restricted to authorized personnel? (YES/NO)*

Comment: It is the collector's responsibility to prevent unauthorized access to collection supplies. To minimize the chances of tampering, donors must not have access to collection site supplies.

Reference: HHS Mandatory Guidelines (subpart E - section 5.5.a.3)

Question A-6*. Does the collection site have the name and telephone number of the designated representative for each federal agency for which specimens are collected? (YES/NO)*

*If **YES**,*

a. Is this information readily available to each collector, in the event that a problem or issue arises during a collection? (YES/NO)

Comment: The collection site must have the name and telephone number of the designated representative for each federal agency readily available, so collectors can contact the agency as needed about problems or issues that arise during the specimen collection procedure.

Reference: HHS Mandatory Guidelines (subpart D - section 4.6.c)

Question A-7. *Does the collection site have procedures to prohibit the following individuals from serving as a specimen collector? (YES/NO)*

*If **NO**, identify the deficient area(s):*

____ *a. Hiring official or donor's immediate supervisor unless there is no feasible alternative and the individual is a trained collector*

____ *b. Co-worker in the same testing pool or who works with the donor on a daily basis*

____ *c. The applicant or employee (i.e., the specimen donor)*

____ *d. Employee of an HHS-certified Instrumented Test Facility (IITF) or HHS-certified laboratory who can link the donor with the specimen drug test results*

____ *e. Relatives or close personal friends of the donor*

Comment: To avoid a conflict of interest, the collection site must prohibit individuals as described in this question from collecting a specimen.

Reference: HHS Mandatory Guidelines (subpart D - section 4.1.b-c, subpart D - section 4.2.a – d)

Section Evaluation

Question A-8. *For the Collection Site Section*:

____ *Serious deficiencies were identified (0 points)*
____ *Deficiencies were identified (1 point)*
____ *No deficiencies were identified (2 points)*

Note: This page is included to facilitate the evaluation of compliance with program requirements. The inspector/reviewer should explain the potential problem or identified non-compliance associated with the checklist questions in this section. Serious deficiencies require immediate corrective action by the collection site to maintain the integrity of the collection process, to maintain the security and integrity of the specimens collected, and to ensure the privacy of the donors.

Describe basis for the above selection:

Section B. Personnel

Collectors

Question B-1. *During interview by the inspection team, did each collector demonstrate a working knowledge of the collection procedures described in the HHS Mandatory Guidelines and any other guidance provided by the federal agency related to specimen collection procedures? (YES/NO)*

*If **NO**, identify the individual(s) and deficient area(s) of knowledge.*

Comment: Prior to performing specimen collections for a federal agency, each collector must demonstrate a working knowledge of the collection procedures described in the HHS Mandatory Guidelines, the HHS Urine Specimen Collection Handbook, and any other guidance provided by the federal agency related to specimen collection procedures. The extent of knowledge is routinely assessed by observing the individual perform a real or mock collection and asking questions concerning practices and procedures. To avoid distracting the collector during a real collection, inspectors should hold questions until after the collection is completed and the donor has left the site.

Reference: HHS Mandatory Guidelines (subpart D - section 4.3.a.1-2)

Question B-2. *Was documentation of training for each collector provided for review during the inspection? (YES/NO)*

*If **NO**, note the collector(s) with missing training documentation.*

Comment: The collection site must provide each collector's training records to the inspectors for review. Inspectors should note any collectors with missing training documentation.

Reference: HHS Mandatory Guidelines (subpart D - section 4.3.c)

Answer questions B-3 through B-8 for the records provided.

Question B-3. *Does each collector maintain their training documentation? (YES/NO)*

Comment: Each collector is required to maintain documentation of current training and refresher training and present it to a federal agency upon request. The collection site may maintain the originals or maintain copies of the training documents. If the collection site provides copies for review, the inspectors may request one or more collectors to provide the originals during the inspection.

Reference: HHS Mandatory Guidelines (subpart D - section 4.3.c and section 4.6.c)

Question B-4. *Did each collector complete initial training before they began collecting specimens for a federal agency? (YES/NO)*

Comment: An individual may not perform specimen collections until his or her training as

a collector has been completed and documented.

Reference: HHS Mandatory Guidelines (subpart D - section 4.3.d)

Question B-5. *Has each collector (as applicable) completed refresher training at least every five years from the date of initial training? (NA/YES/NO)*

Comment: Each collector must complete refresher training every five years.

Reference: HHS Mandatory Guidelines (subpart D - section 4.3.b)

Question B-6. *Do the initial and refresher training records for each collector document training on the following subjects? (YES/NO)*

*If **NO**, identify the individual and records and check the deficient area(s):*

____ *a. The steps to correctly perform a collection*

____ *b. The proper completion and distribution of the Federal CCF*

____ *c. Problem collections*

____ *d. Fatal and correctable flaws and how to correct problems in collections*

____ *e. Collector responsibilities to maintain the integrity of the collection process, to protect the privacy of donors, to ensure the security and integrity of specimens, and to maintain proper conduct*

Comment: A qualified trainer for collectors must perform training on these topics during initial collector training and during refresher training at least every five years. Training documentation should clearly indicate these training topics on the certificate or in the training manual.

Reference: HHS Mandatory Guidelines (subpart D - section 4.3.a.3)

Question B-7. *Do the initial and refresher training records for each collector document their proficiency in collections by successful completion of five (5) consecutive error-free mock collections? (YES/NO)*

*If **NO**, identify the individual and records and check the deficient area(s):*

____ *a. One uneventful scenario*

____ *b. One insufficient specimen quantity scenario*

____ *c. One temperature is out of range scenario*

____ *d. One scenario in which the donor refuses to sign the Federal CCF*

____ *e. One scenario in which the donor refuses to initial the tamper-evident bottle label/seal*

Comment: Initial and refresher training must include the successful completion of five (5) consecutive error-free mock collections (i.e., one uneventful scenarios, one insufficient specimen quantity scenario, one where the temperature is out of range, one in which the donor refuses to sign the Federal CCF, and one in which the donor refuses to initial the tamper-evident bottle label/seal).

Reference: HHS Mandatory Guidelines (subpart D - section 4.3.a.4.i)

Question B-8. *Do the initial and refresher training records for each collector include the following? (YES/NO)*

*If **NO**, identify the individual and records and check the deficient area(s):*

____ *a. Documentation that the training was conducted in person or by means allowing real-time observation and interaction between trainer and trainee.*

____ *b. Written attestation by the trainer that the mock collections were error-free.*

____ *c. Documentation of the trainer's qualifications at the time of the training.*

Comment: A qualified trainer for collectors must monitor and evaluate the trainee and must attest in writing that the five (5) consecutive mock collections were error-free. Training records must document that training was either conducted in person by a qualified trainer or by a means allowing real-time observation and interaction between trainer and trainee. The records should document the trainer's qualifications at the time of the training on the certificate or in the training manual.

Reference: HHS Mandatory Guidelines (subpart D - section 4.3.a.4.ii, and subpart D - section 4.5.c)

Collector Trainers

Answer the remaining Section B questions if collection site employees serve as collector trainers.

Question B-9. *During interview by the inspection team, did each collector trainer demonstrate a working knowledge of the collection procedures described in the HHS Mandatory Guidelines and any other guidance provided by the federal agency related to the collection procedures? (YES/NO)*

Comment: Each collector trainer must demonstrate a working knowledge of the collection procedures described in the HHS Mandatory Guidelines, the HHS Urine Specimen Collection Handbook, and any other guidance provided by the federal agency related to specimen collection procedures prior to performing specimen collections.

Reference: HHS Mandatory Guidelines (subpart D – section 4.3.a.1-2)

Question B-10. *Was documentation of training for each trainer provided for review during the inspection? (YES/NO)*

*If **NO**, note the trainer(s) with missing training documentation.*

Comment: For each staff member performing collector training, the collection site must provide training records to the inspectors for review. Inspectors should note any trainers with missing training documentation.

Reference: HHS Mandatory Guidelines (subpart D - section 4.5.c)

Complete the remaining Section B questions for the records provided.

Question B-11. *Does each trainer maintain their training documentation? (YES/NO)*

Comment: Each trainer is required to maintain documentation of initial and refresher training and present it to a federal agency upon request. The collection site may maintain the originals or maintain copies of the training documents. If the collection site provides copies for review, the inspectors may request one or more trainers to provide the originals during the inspection.

Reference: HHS Mandatory Guidelines (subpart D - section 4.5.c)

Question B-12. *Do the training records for each collector trainer document at least one of the following qualifications? (YES/NO)*

- *The trainer is qualified as a collector and has regularly conducted drug test collections for a period of at least one year,*

- *The trainer successfully completed a "train the trainer" course given by an organization (e.g., manufacturer, private entity, contractor, or federal agency)*

Comment: To be qualified as a collector trainer, the individual must be qualified as a collector and have regularly conducted drug test collections for at least one year OR must have completed a "train the trainer" course provided by an organization (e.g., manufacturer, private entity, contractor, or federal agency).

Reference: HHS Mandatory Guidelines (subpart D - section 4.5.a.1 - 2)

Question B-13. *Has each trainer (as applicable) completed refresher training at least every five years from the date of initial training? (YES/NO)*

Comment: Each collector trainer must undergo refresher training at least every five years.

Reference: HHS Mandatory Guidelines (subpart D - section 4.5.b)

Section Evaluation

Question B-14. *For the Personnel Section*:

____ *Serious deficiencies were identified (0 points)*
____ *Deficiencies were identified (1 point)*
____ *No deficiencies were identified (2 points)*

Note: This page is included to facilitate the evaluation of compliance with program requirements. The inspector/reviewer should explain the potential problem or identified non-compliance associated with the checklist questions in this section. Serious deficiencies require immediate corrective action by the collection site to maintain the integrity of the collection process, to maintain the security and integrity of the specimens collected, and to ensure the privacy of the donors.

Describe basis for the above selection:

Section C. Specimen Collection Procedures

Question C-1. *Does the collector prepare the restroom to deter the dilution or substitution of a specimen? (YES/NO)*

Required steps:

- *Placing bluing agent in the toilet or turning off the water supply and flushing the toilet*

- *Securing any other water source in the enclosure where urination occurs*

Comment: Collectors must prepare the collection site prior to specimen collection to deter dilution or substitution of the specimen. The collector must ensure that there is bluing agent in the toilet or toilet tank so that water always remains blue. If bluing agent is not available or the toilet has an automated flushing system, the collector must turn off the water supply and flush the toilet to remove any water in the toilet. The collector must also turn off or secure other water supply inside the restroom where the collection is taking place. If the water supply cannot be secured or turned off, the collector must perform a monitored collection as described in Questions D-6 through D-8.

Reference: HHS Mandatory Guidelines (subpart H – section 8.2.a-b)

Question C-2. *Does the collector begin the collection without delay once the donor arrives at the collection site? (YES/NO)*

Comment: The collector must begin the collection procedure once the donor arrives at the collection site. The collection process must not be delayed because an authorized employer or employer representative is late arriving or because the donor indicates that they are not able to urinate.

Reference: HHS Mandatory Guidelines (subpart H – section 8.3.b)

Question C-3. *When a donor does not arrive at the collection site at the assigned time for the drug test, does the collector contact the federal agency representative to obtain guidance on the appropriate action to be taken? (YES/NO)*

Comment: If the donor is required to arrive within a window of time and is outside of that window specified by the agency, the collector must contact the federal agency representative to obtain guidance on the appropriate action to be taken when a donor fails to arrive at the collection site on time.

Reference: HHS Mandatory Guidelines (subpart H – section 8.3.a)

Question C-4. *Does the collector perform only one specimen collection at a time? (YES/NO)*

Comment: To ensure specimen integrity, collectors must perform one collection at a time.

Reference: HHS Mandatory Guidelines (subpart E - section 5.5.a.2)

Question C-5. *Does the collector properly verify donor identity? (YES/NO)*

Proper forms of identification include:

- *Driver's license*
- *Employee badge issued by the employer*
- *Photo identification issued by a federal, state, or local government agency*

Comment: The collector must verify the identity of the donor by requesting photo identification (i.e., drivers license, employee badge issued by the employer, or other photo identification issued by federal, state, or local government) from the donor prior to specimen collection. If the donor does not have proper photo identification, the collector must contact the supervisor of the donor or the federal agency representative who can positively identify the donor. If the identity of the donor cannot be established, the collector must stop the collection procedure.

Reference: HHS Mandatory Guidelines (subpart H – section 8.3.c)

Question C-6. *Does the collector provide identification to the donor when requested? (YES/NO)*

Comment: The collector must provide identification (e.g., employee badge, employee list) to the donor if requested.

Reference: HHS Mandatory Guidelines (subpart H – section 8.3.d)

Question C-7*. Does the collector describe the basic collection procedures to the donor and instruct the donor that they may read the instructions for completing the Federal CCF? (YES/NO)*

Comment: The collector must describe the basic collection procedures to the donor and instruct the donor that they may read the instructions for completing the Federal CCF.

Reference: HHS Mandatory Guidelines (subpart H – section 8.3.e - f)

Question C-8. *Does the collector answer any reasonable and appropriate questions that the donor has about the collection process? (YES/NO)*

Comment: The collector must answer any reasonable and appropriate questions that the donor has about the collection process.

Reference: HHS Mandatory Guidelines (subpart H – section 8.3.g)

Question C-9. *Does the collector complete the required information in Step 1 of the Federal CCF? (YES/NO)*

Comment: The collector must ensure that Step 1 of the Federal CCF is completed prior to specimen collection. The employer, Medical Review Officer (MRO), collection site, and collector information may be preprinted or handwritten. The collector records the information if it is not present. The collector enters the donor identification information after verifying donor identity and enters a REMARK in Step 2 if the donor refuses to provide his or her social security number (SSN) or employee identification number. The collector marks the appropriate checkboxes to indicate the testing authority under which the specimen is being collected and the reason for testing. The collector also indicates the drug tests to be performed.

Reference: Federal CCF (back of copy 5) and HHS Collection Handbook

Question C-10. *Does the collector take the following steps to deter specimen tampering? (YES/NO)*

*If **NO**, check the deficient step(s):*

____ *a. Ask the donor to remove any unnecessary outer clothing (e.g., coat, jacket, hat, etc.)*

____ *b. Ask the donor to leave all other personal belongings (e.g., briefcase, purse) with the outer clothing or in another secured location*

____ *c. Direct the donor to empty their pockets and display the items for inspection*

____ *d. Secure any items that could be used to adulterate a specimen that appears to have been inadvertently brought by the donor to the collection site*

____ *e. Direct the donor to wash and dry their hands under the collector's supervision*

Comment: The collector must take the steps listed in this question to deter specimen tampering.

The donor is not required to remove boots or a hat or head covering that the donor

refuses to remove based on religious practice, unless the collector suspects that the donor is concealing a potential adulterant or substitution produce in the garments.

The collector must ensure that all personal belongings (e.g., briefcase, purse) remain with the outer clothing. The donor may retain their wallet. The collection site may have procedures to ensure security of the donors' belongings (e.g., itemized receipt; storage in a lockable cabinet; envelope, box, or container sealed with tamper-evident tape initialed/signed by the donor).

If the collectors sees no items from the donor's pockets that could be used to adulterate or substitute the specimen, the donor is permitted to place those items back in their pockets and continue with the collection procedure. The collector must secure any items found that could be used to adulterate or substitute a specimen and appear to have been inadvertently brought by the donor to the collection site. If an item is found that indicated that the donor intended to adulterate or substitute the specimen, this is considered a refusal to test. The collector must stop the collection and report the refusal to test to the federal agency by a means ensuring immediate receipt (e.g., telephone, email, or secure fax) described in Questions D-17. All items are returned to the donor after the collection. If the donor refuses to display the items in his or her pockets, this is considered a refusal to test. The collector must report the refusal to test as outlined in Question D-17.

The collector must direct the donor to wash and dry their hands under the collector's supervision. Liquid soap is preferred over bar soap as the donor may 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, cleaning agent, or any other items that could be used to adulterate or substitute the specimen.

Reference: HHS Mandatory Guidelines (subpart H –section 8.3.h, section 8.3.h.1 - 4, and section 8.3.h.5.i)

Question C-11. *Does the collector note any unusual appearance or behavior of the donor on the Federal CCF? (YES/NO)*

Comment: The collector must note any unusual appearance or behavior of the donor on the Federal CCF. If the collector detects conduct that indicates an attempt to tamper with the specimen, this is considered a refusal to test. The collector must stop the collection and report the refusal to test to the federal agency as described in Question D-17.

Reference: HHS Mandatory Guidelines (subpart H – section 8.4.c)

Question C-12. *Does the collector give the donor the following collection instructions? (YES/NO)*

*If **NO**, check the deficient area(s):*

____ *a. Provide at least 45 mL of urine*

____ *b. Do not flush the toilet*

____ *c. Provide the specimen in a reasonable time (set by the collector)*

____ *d. Return with the specimen as soon as they have finished providing the specimen*

Comment: The collector must give the donor the instructions listed in this question. The collector may set a reasonable time limit for voiding. The collector may inform the donor that the specimen temperature must be read within four minutes after completing the void, and that longer wait periods may cause the specimen to be out of range and may necessitate an observed collection.

Reference: HHS Mandatory Guidelines (subpart H – section 8.4.b, and subpart H – section 8.4.b.2)

Question C-13*. Are unauthorized personnel prohibited from entering the collection site during the collection procedure? (YES/NO)*

Comment: Except in the case of an observed specimen collection, neither the collector nor anyone else may enter the restroom with the donor. In the case of a monitored collection, the monitor may enter a multi-stall restroom, but must stay outside the stall.

Reference: HHS Mandatory Guidelines (subpart E - section 5.5.a.1; subpart H – section 8.1.a)

Question C-14. *Are only the collector and the donor allowed to handle the unsealed specimen? (YES/NO)*

Comment: The collector must ensure that only the collector and donor handle the unsealed specimen.

Reference: HHS Mandatory Guidelines (subpart E - section 5.5.a.4)

Question C-15. *Do both the collector and the donor maintain visual contact with the specimen from the time the specimen is transferred to the collector until specimen bottles have been sealed for shipment? (YES/NO)*

Comment: Both the collector and the donor must maintain visual contact with the specimen from the time the specimen is transferred from the donor to the collector until the specimen bottles have been sealed for shipment to the testing facility.

Reference: HHS Mandatory Guidelines (subpart H – section 8.5.b)

Completion of a Collection

Question C-16*. After receiving the specimen from the donor, whenever practical, does the collector allow the donor to wash their hands and to flush the toilet? (YES/NO)*

Comment: After the collector has received the specimen from the donor, the donor may be allowed to wash their hands and to flush the toilet. Prior to flushing the toilet, the collector may inspect the toilet for any materials indicative of specimen tampering.

Reference: HHS Mandatory Guidelines (subpart H – section 8.5.c)

Question C-17. *Does the collector check the specimen temperature within four minutes after receiving the specimen from the donor and check the appropriate box in Step 2 of the Federal CCF? (YES/NO)*

Comment: The collector must check the temperature of the specimen within four minutes after receiving the specimen from the donor. The temperature measuring device must be able to accurately read the temperature and must not contaminate the specimen. The collector must indicate on the CCF whether the specimen was within the acceptable temperature range (i.e., 90° - 100°F; 32° – 38°C). If the specimen is outside the acceptable range, this is reason to believe that the donor may have adulterated or substituted the specimen, and another specimen must be collected under direct observation as described in Questions D-1 through D-5. 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 as a refusal to test. The collector reports a refusal to test as outlined in Question D-17.

> **Note:** The second collection using the direct observed collection procedure must be performed using a new collection kit (i.e., new collection container and Federal CCF). Prior to beginning the direct observed collection, the collector completes the first collection. The collector must record a comment on the Remarks line in Step 2 of both Federal CCF's (i.e., from the first and second specimens) indicating why two specimens were collected and including a cross-reference to the first specimen identification number on the Federal CCF for the second specimen. The specimen with unacceptable temperature must be forwarded to an HHS-certified laboratory (not an IITF) 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), the collector must discard the urine collected.*] The collector must begin a second collection using the same Federal CCF and the same procedures (not directly observed) and use a new collection container for the second collection. If the donor provides less than 45 mL for the second specimen, the collector must follow the insufficient specimen procedures, as applicable. The second specimen is not sent for testing if the volume is less than 45 mL.

Reference: HHS Mandatory Guidelines (subpart H – section 8.5.d.1-2)

Question C-18. *Does the collector inspect the specimen for adulteration or substitution by examining the physical characteristics of the urine? (YES/NO)*

Comment: The collector must inspect the specimen for signs of adulteration or substitution by examining the physical characteristics of the urine. The collector should note any unusual color, foreign objects, unusual odor, or other signs of adulteration (e.g., excessive foaming when shaken). Any unusual finding must be noted on the Federal CCF.

Any specimen suspected of not being a valid urine specimen is forwarded to the testing facility. When there is reason to believe the donor has adulterated or substituted the specimen, another specimen must be collected under direct observation as described in Questions D-1 through D-5. 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 as a refusal to test. The collector reports a refusal to test as outlined in Question D-17.

Note: The second collection using the direct observed collection procedure must be performed using a new collection kit (i.e., new collection container and Federal CCF). Prior to beginning the direct observed collection, the collector completes the first collection. The collector must record a comment on the Remarks line in Step 2 of both Federal CCF's (i.e., from the first and second specimens) indicating why two specimens were collected and including a cross-reference to the first specimen identification number on the Federal CCF for the second specimen. The specimen with abnormal physical characteristics and its Federal CCF must be forwarded to an HHS-certified laboratory (not an IITF), regardless of the specimen volume. If the donor provides less than 45 mL for the second specimen, the collector must follow the insufficient specimen procedures, as applicable. The second specimen is not sent for testing if the volume is less than 45 mL.

Reference: HHS Mandatory Guidelines (subpart H – section 8.5.e.1-2)

Question C-19. *Does the collector check the specimen volume to ensure that the specimen contains at least 45 mL of urine? (YES/NO)*

Comment: The collector must verify that the specimen volume is at least 45 mL. If the specimen volume is sufficient, the collector should continue with the collection procedure.

If the specimen volume is not at least 45 mL, the collector must discard the specimen and immediately collect another specimen using a new collection container and the same Federal CCF. **The collector must never combine urine collected from separate voids to create a sufficient specimen.**

If the donor is unable to provide a second urine specimen, the collector follows the *Insufficient Specimen* procedures described in Questions D-9 through D-15. 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 as a refusal to test. The collector reports a refusal to test as outlined in Question D-17.

Reference: HHS Mandatory Guidelines (subpart H – section 8.5.f. 1-2)

Question C-20. *In the presence of the donor, does the collector pour at least 30 mL into "Bottle A" and at least 15 mL into "Bottle B"? (YES/NO)*

Comment: The collector should unwrap the specimen bottles (i.e., Bottle A and Bottle B) in the donor's presence. The collector must pour the urine from the collection container into each specimen bottle and cap each bottle in the presence of the donor. At least 30 mL must be poured into Bottle A and at least 15 mL into Bottle B.

Reference: HHS Mandatory Guidelines (subpart H – section 8.8.b)

Question C-21. *Does the collector discard excess urine (unless it is used for a clinical test as part of a physical examination required by a federal agency)? (YES/NO)*

Comment: After the specimen bottles have been appropriately filled, the collector must discard excess urine left in the collection container. No further testing may be done with the excess urine (e.g., specimen validity testing). The only exception is if the collection was conducted in conjunction with a physical examination required by the federal agency. In this case, the excess urine may be used for the clinical tests.

Reference: HHS Mandatory Guidelines (subpart H – section 8.8.j)

Question C-22. *In the presence of the donor, does the collector place the appropriate tamper-evident label/seal from the Federal CCF over the lid/cap of each bottle to ensure that the lid/cap cannot be removed without destroying the label/seal? (YES/NO)*

Comment: The collector must place the tamper-evident label/seal from the Federal CCF over the lid/cap of each bottle to ensure that the lid/cap cannot be removed without destroying the label/seal. **This must be performed in the presence of the donor.** The "**A**" label is used for the bottle containing the larger volume (i.e., at least 30 mL urine) and the "**B**" label is used for the bottle containing the smaller volume (i.e., at least 15 mL).

Reference: HHS Mandatory Guidelines (subpart H – section 8.8.c)

Question C-23. *If the tamper-evident label/seal does not adhere to the bottle, does the collector apply the unacceptable label/seal to the bottle, and apply a second, separate tamper-evident seal to seal the specimen bottle? (YES/NO)*

Comment: In some cases, the tamper-evident label/seal may not adhere to the bottle or the label/seal may be accidentally broken or damaged during the collection process. In these instances, the collector must apply the original (unacceptable) labels/seals and apply a second separate tamper-evident seal to each specimen bottle. The additional seal should be placed perpendicular to the original label/seal to avoid obscuring information on the label/seal (which is from the associated Federal CCF). The collector must initial and date the second seal, and request that the donor initial the second seal. If the donor refuses to initial the second seal, the collector should note this refusal on the Remarks line in Step 2 and continue with the collection process. This is not considered a refusal to test.

The collector should provide a comment on the Remarks line in Step 2 of the Federal CCF explaining why a second seal was used.

Reference: HHS Collection Handbook

Question C-24*. Does the collector record the date of the collection on the bottle seals after placing them on the bottles? (YES/NO)*

Comment: The collector must write the date of the collection on the labels/seals after placing them on the specimen bottles (i.e., Bottle A and Bottle B).

Reference: HHS Mandatory Guidelines (subpart H – section 8.8.c)

Question C-25*. Does the collector ask the donor to initial the specimen bottle seals after placing them on the bottles? (YES/NO)*

Comment: After placing the labels/seals on the bottles, the collector must direct the donor to initial the labels/seals taking care to avoid damage. If the donor refuses to initial the labels/seals, the collector should note this refusal on the Remarks line in Step 2 and continue with the collection process. This is not considered a refusal to test.

Reference: HHS Mandatory Guidelines (subpart H – section 8.8.d)

Question C-26. *Does the collector instruct the donor to read and sign the donor certification statement and to fill out the donor portion in Step 5 on Copy 2 of the Federal CCF? (YES/NO)*

Comment: The collector requests that the donor fill out the donor portion in Step 5 on Copy 2 of the Federal CCF by printing their name, and providing their date of birth, and day and evening telephone numbers. If the donor refuses to provide the information, the collector should print the donor's name where indicated.

The collector requests that the donor read, sign, and date the donor statement certifying that the specimen identified was collected from him or her. If the donor refuses to sign

the certification statement, the collector should note this refusal on the Remarks line in Step 2 of the Federal CCF and continue with the collection process. This is not considered a refusal to test.

For electronic CCFs or combination electronic and paper CCFs: Some of the items (i.e., date of birth, printed name and telephone numbers) may already have been entered in to the ECCF system prior to the collection. 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.

Reference: HHS Mandatory Guidelines (subpart H – section 8.8.f)

Question C-27. *Does the collector complete the collector chain of custody section in Step 4 on Copy 1 of the Federal CCF? (YES/NO)*

Comment: The collector must complete Step 4 on Copy 1 of the Federal CCF by signing and printing their name, recording the date of the collection, and indicating the delivery service to which the specimen bottles and CCF will be released.

Reference: HHS Mandatory Guidelines (subpart H – section 8.8.g)

Question C-28*. Does the collector place the sealed specimen bottles inside the leak-resistant container, seal the container, and include Copy 1 in the package with the specimen (i.e., in a compartment separate from the specimen bottles)? (YES/NO)*

Comment: The collector places both specimen bottles inside the leak-resistant container and seals the container.

For paper CCFs and combination electronic and paper CCFs: the collector places Copy 1 in the specimen package (i.e., in a compartment separate from the specimen bottles). **Note**: 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 Federal CCFs: the collector must either include a printed copy of Copy 1 with the specimen OR must apply a label to the outside of the specimen package with the specimen identification number, test facility name and contact information, and the collection site name and contact information.

Reference: HHS Mandatory Guidelines (subpart H – section 8.8.h) and HHS Collection Handbook

Question C-29. *Does the collector provide Copy 5 of the Federal CCF to the donor? (YES/NO)*

Comment: The collector gives Copy 5 of the Federal CCF to the donor. This may be a printed copy or a copy provided electronically after the collection. The collector reminds the donor that they may list any prescription medications on the back of Copy 5 or on a separate sheet of paper. This information may help the donor remember which medications they may have taken near the time of the collection, if contacted later by the MRO.

Reference: HHS Collection Handbook

Question C-30. *Does the collector prepare the sealed tamper-resistant package containing the specimen bottles and Federal CCF for transport to the HHS-certified test facility (i.e., IITF or laboratory)? (YES/NO)*

Comment: The collector places the sealed specimen package into a shipping container (e.g., box or express carrier mailer). Several specimen packages may be placed in one shipping container. The collector then seals the container. It is not necessary to use a shipping container if the specimen packages are to be hand-delivered to the testing facility.

Note: If the tamper-evident label/seal from the Federal CCF is broken on the specimen bottle after the donor leaves the collection site, the collection must be cancelled. The collector notifies the federal agency's designated representative that the label/seal was broken on the specimen bottle(s).

Reference: HHS Collection Handbook

Question C-31*. Are the specimen bottles and Federal CCF appropriately safeguarded until they are retrieved for transport to the HHS-certified test facility (i.e., IITF or laboratory)? (YES/NO)*

Comment: If the specimens are not shipped immediately, the collector is responsible for ensuring specimen security. For specimens not in a shipping container, the collector must take necessary steps to prevent any possible tampering or access by unauthorized personnel. Specimen packages in a sealed shipping container should be protected against theft or damage prior to pick-up by the designated delivery service.

Reference: HHS Mandatory Guidelines (subpart H – section 5.2.c and 8.8.i) and HHS Collection Handbook

Question C-32. *Does the collector send Copy 2 of the Federal CCF to the Medical Review Officer (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? (YES/NO)*

Comment: The collector must send Copy 2 of the Federal CCF to the MRO and Copy 4

to the federal agency's representative within 24 hours after the collection or during the next business day. Acceptable methods of transmitting the Federal CCF include faxing to a secure fax machine, sending a scanned image to a secure computer, or sending by mail or courier.

Reference: HHS Collection Handbook

Question C-33. *Are specimens submitted to an HHS-certified test facility (i.e., IITF or laboratory) within 24 hours after the collection or during the next business day? (YES/NO)*

Comment: Specimens must be submitted to the testing facility within 24 hours after the collection or during the next business day.

Reference: HHS Mandatory Guidelines (subpart H – section 8.8.i) and HHS Collection Handbook

Section Evaluation

Question C-34. *For the Specimen Collection Procedures Section*:

____ *Serious deficiencies were identified (0 points)*
____ *Deficiencies were identified (1 point)*
____ *No deficiencies were identified (2 points)*

Note: This page is included to facilitate the evaluation of compliance with program requirements. The inspector/reviewer should explain the potential problem or identified non-compliance associated with the checklist questions in this section. Serious deficiencies require immediate corrective action by the collection site to maintain the integrity of the collection process, to maintain the security and integrity of the specimens collected, and to ensure the privacy of the donors.

Describe basis for the above selection:

Section D. Collection Problems

Direct Observed Collections

Question D-1. *Does the collector initiate a direct observed collection in the following situations? (YES/NO)*

*If **NO**, check the deficient area(s):*

____ *a. Specimen temperature is outside the acceptable range*

____ *b. Specimen appearance indicative of tampering (abnormal physical characteristic such as unusual color, excessive foaming when shaken, unusual odor)*

____ *c. Donor conduct indicates an attempt to adulterate or substitute the specimen, and the donor has already provided a specimen*

Comment: The collector initiates a direct observed specimen for the reasons listed above.

Reference: HHS Mandatory Guidelines (subpart H – section 8.9.b.1-2)

Question D-2. *Does the collector take the following steps before conducting a direct observed collection? (YES/NO)*

*If **NO**, check the deficient step(s):*

____ *a. Contact a collection site supervisor for concurrence with the collector's decision for a direct observed collection*

____ *b. Explain to the donor why a direct observed collection is being conducted*

____*c. Inform the donor that the gender of the observer will match the donor's gender, which is determined by the donor's gender identity*

Comment: If a direct observed collection is warranted for one or more of the reasons listed in Question D-1, the collector must contact the collection site supervisor for concurrence in advance of any decision to obtain a specimen under direct observation. Once the decision for an observed collection has been made, the collector must explain to the donor why a direct observed collection is being conducted. The collector informs the donor that the gender of the observer will be the same as the donor's gender, which is determined by the donor's gender identity.

Reference: HHS Mandatory Guidelines (subpart H – section 8.9.c and 8.10.a-b) and

Question D-3. *Before an individual is allowed to serve as the observer for a direct observed collection, does a collector/collection site supervisor provide training on the following subjects? (YES/NO)*

*If **NO**, identify the individual and records and check the deficient area(s):*

____ *a. The steps necessary to perform a direct observed collection correctly*

____ *b. Maintaining visual contact with the collection container throughout the collection process, to maintain the integrity and security of the specimen*

____ *c. Ensuring the privacy of the donor*

____ *d. Observing the collection in a professional manner, to minimize discomfort of the donor*

____ *e. Avoiding conduct that could be interpreted as offensive or inappropriate*

Comment: In direct observed specimen collections, an observer who is the same gender as the donor must accompany the donor into the restroom during the specimen collection. The observer must directly watch the urine exit from the donor's body into the collection container. The use of mirrors or video cameras is not permitted.

The collector asks the donor to identify the donor's gender on the Federal CCF and initial it. The donor will then be provided an observer whose gender matches the donor's gender. The collector documents the observer's name and gender on the Federal CCF.

Before an individual is allowed to serve as an observer for a direct observed specimen collection, a collector/collection site supervisor must provide training on all items listed in this question. The observer is not required to be a trained collector.

Note: If the donor fails to follow the observer's instructions related to the direct observed collection, this is considered a refusal to test. The collector reports the refusal to test as outlined in Question D-17.

After the donor has completed urinating into the collection container, the donor and observer leave the restroom together and the donor hands the collection container directly to the collector. The observer must never touch or handle the collection container unless the observer is also serving as the collector. The observer must maintain visual contact with the collection container until the donor hands the container to the collector. If the collector serves as the observer, the collector may receive the collection container from the donor inside the restroom.

Reference: HHS Mandatory Guidelines (subpart D - section 4.4.a-c and subpart H -

section 8.10.a-d)

Question D-4. *Does the collector ensure that the observer for each direct observed collection meets the following requirements? (YES/NO)*

- *Trained in direct observed specimen collection procedures*
- *Same gender as the donor*

Comment: The collector must ensure that the observer has received training in direct observed specimen collection procedures training (i.e., on all items listed in Question D-3). 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.**

Reference: HHS Mandatory Guidelines (subpart D - section 4.4.a-c)

Question D-5. *Does the collector properly document the direct observed collection in Step 2 of the Federal CCF? (YES/NO)*

*If **NO**, check the deficient step(s):*

____ *a. Mark the checkbox for an observed collection*

____ *b. Record the name and gender of the observer on the Remarks line*

____ *c. Record the reason for the observed collection on the Remarks line*

Comment: The collector documents the direct observed collection on the Federal CCF as listed above: marking the checkbox for an observed collection, recording the observer's name and gender, and recording the reason for the observed collection.

Reference: HHS Mandatory Guidelines (subpart H – section 8.10.d).

Monitored Collections

Question D-6. *Does the collector initiate a monitored collection in the following situations? (YES/NO)*

- *The collection is being conducted in a public restroom*
- *The restroom used for the collection has a water source that cannot be disabled or secured*

Comment: Monitored collections are performed when the federal agency's designated collection site is not available and there is an immediate need to collect a specimen (e.g., accident investigation). A monitored collection must be performed if a public

restroom is being used for the collection or if the restroom has a water source that cannot be disabled or secured.

Note: If a donor refuses to permit a monitored collection, the collector must report a refusal to test as outlined in Question D-17.

The procedure for a monitored collection is the same as for a routine collection, except an individual monitors the collection by checking for signs that the donor may be tampering with the specimen. The monitor must accompany the donor into the restroom and secure the restroom to ensure that no one else can enter during the collection process. The monitor must remain in the restroom, but outside the stall, while the donor is providing the specimen and must listen for signs of tampering. The monitor must not watch the donor urinate into the specimen container. After the donor has completed urinating in the collection container, the donor and monitor leave the restroom together and the donor hands the collection container to the collector. The monitor must never handle or touch the collection container unless the monitored also serves as the collector. The monitor must maintain visual contact with the collection container until the donor has handed the container to the collector. If the collector serves as the monitor, the collector may receive the collection container from the donor inside the restroom.

Note: If there are signs of tampering, the monitor must immediately report this to the collector so that the collector can begin to collect a second specimen using the direct observed specimen collection procedures described under Questions D-1 through D-5.

Reference: HHS Mandatory Guidelines (subpart H – section 8.12)

Question D-7. *Does the collector ensure that the monitor for each monitored collection meets at least one of the following requirements? (YES/NO)*

- *Same gender as the donor*
- *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*

Comment: The collector must ensure that the monitor's gender is the same as the donor's gender, which is determined by 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 does not need to be a trained collector.

Reference: HHS Mandatory Guidelines (subpart H – section 8.12)

Question D-8. *Does the collector record the name of the monitor (if not the collector) on the Remarks line in Step 2 on Copy 1 of the Federal CCF? (YES/NO)*

Comment: If the collector is not serving as the monitor, the collector must record the name of the monitor on the Remarks line in Step 2 on Copy 1 of the Federal CCF.

Reference: HHS Mandatory Guidelines *(*subpart H – section 8.12.f)

Insufficient Specimen

Question D-9. *When the donor has demonstrated that they are unable to provide a sufficient specimen, does the collector offer the donor a reasonable amount of fluid to drink (e.g., an 8 ounce glass of water every 30 minutes, not to exceed 40 ounces over a period of 3 hours)? (YES/NO)*

Comment: The collector must begin the collection regardless of whether the donor states that they cannot provide a specimen. The collector requests that the donor enter the restroom and attempt to provide a specimen. The donor demonstrates their inability to provide a specimen by returning from the restroom with an empty specimen collection container.

If the donor indicates that they may be able to provide a specimen if given more time, the collector should offer the donor a reasonable amount of fluid to drink distributed reasonably over three hours (e.g., an 8 ounce glass of water every 30 minutes, not to exceed 40 ounces over a period of 3 hours). The donor is not required to drink fluids during this time period. It is recommended that the collector allow sufficient time to only have one additional attempt rather than documenting several unsuccessful attempts.

Note: If the donor refuses to attempt to provide a specimen or leaves the collection site before the process is completed, this is considered a refusal to test. The collector reports the refusal to test as outlined in Question D-17.

Reference: HHS Mandatory Guidelines (subpart H – section 8.5.f.2.i and subpart H – section 8.6) and HHS Collection Handbook

Question D-10. *Does the collector allow the donor up to three hours to provide a sufficient specimen? (YES/NO)*

Comment: The collector must allow three hours for the donor to provide a sufficient specimen. The collector should be sensitive to how frequently the donor is asked to provide a specimen

Reference: HHS Mandatory Guidelines (subpart H – section 8.5.f.2.i)

Question D-11. *Do collection procedures prohibit combining urine collected from separate voids to create a specimen of sufficient volume? (YES/NO)*

Comment: The collector must **not**, *under any circumstances*, combine urine collected

from separate voids to create one specimen of sufficient volume.

Reference: HHS Mandatory Guidelines (subpart H – section 8.5.f)

Question D-12. *Does the donor remain under the direct observation of the collector to prevent the donor from possibly compromising the collection process? (YES/NO)*

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

Reference: HHS Collection Handbook

Question D-13. *Does the collector record the time of each attempt to provide a sufficient volume of specimen (e.g., on the Remarks line of the Federal CCF)? (YES/NO)*

Comment: The collector must record the time of each attempt by the donor to provide a sufficient volume of specimen (e.g., on the Remarks line of the Federal CCF).

Reference: HHS Collection Handbook

Question D-14. *Does the collector discontinue the collection procedure in the following situations? (YES/NO)*

- *The donor states that they are unable to provide a specimen*
- *The donor has not provided sufficient volume of specimen in three hours from the time of the donor's first attempt*

Comment: If the donor states they are unable to provide a specimen or if the donor has not provided a sufficient specimen in three hours from the first attempt, the collector is to discontinue the collection and direct the donor to leave the collection site.

Reference: HHS Mandatory Guidelines (subpart H – section 8.5.f.2.iii and 8.6.b.2)

Question D-15. *When the donor has not provided a sufficient specimen, does the collector end the collection procedure and take the following steps? (YES/NO)*

*If **NO**, check the deficient area(s):*

____ *a. Mark the "None Provided" checkbox in Step 2 of the Federal CCF*

____ *b. Record the reason for not collecting the specimen on the Remarks line in Step 2 of the Federal CCF*

____ *c. Notify the agency's designated representative for authorization to collect an alternate specimen or follow the standard protocol from the federal agency*

____ *d. Discard the urine collected (if any)*

____ *e. Discard Copy 1 of the Federal CCF (no valid specimen was collected) and maintain Copy 3 in the collection records*

____ *f. Distribute the remaining Federal CCF copies within 24 hours or the next business day:*

- *Send Copy 2 to the MRO*
- *Send Copy 4 to the federal agency's designated representative*

Comment: When a donor has not provided a sufficient specimen, the collector must follow all steps listed above. If an alternate specimen is authorized, the collector may begin the collection procedure for the alternate specimen in accordance with the Mandatory Guidelines for Federal Workplace Drug Testing Programs using the alternate specimen (i.e., oral fluid). 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.

Reference: HHS Mandatory Guidelines (subpart H – section 8.5.f.2.iii and 8.6.b.1-2)

Refusal to Test

Question D-16. *Does the collector report a "refusal to test" in the following situations? (YES/NO)*

*If **NO**, check the deficient area(s):*

____ *a. The donor fails to appear for any test (except a pre-employment test) within a reasonable time as determined by the federal agency*

____ *b. The donor fails to provide a specimen (e.g., urine or another authorized alternate specimen type)*

____ *c. The donor fails to cooperate with any part of the testing process (e.g., refuses to empty pockets, disrupts the collection process, fails to wash hands when directed by the collector)*

____ *d. The donor fails to allow a direct observed collection when required*

____ *e. The donor fails to follow the observer's instructions related to the direct observed collection*

____ *f. The donor fails to allow a monitored collection when required*

____ *g. The donor brings materials to the collection site for the purpose of adulterating, substituting, or diluting the specimen*

____ *h. The donor attempts to adulterate, substitute, or dilute the specimen*

____ *i. The donor leaves the collection site before completion of the collection (except for leaving before the collection has begun for a pre-employment test)*

____ *j. The donor possesses or wears a prosthetic or other device that could be used to interfere with the collection process*

____ *k. The donor admits to the collector that they have adulterated or substituted their specimen*

Comment: A federal agency will take adverse action against an employee whose drug test specimen is reported as a refusal to test. The collector must report a refusal to test in the situations listed above.

Reference: HHS Mandatory Guidelines (subpart A – section 1.7.a.1-13)

Question D-17. *When reporting a "refusal to test," does the collector take the following steps? (YES/NO)*

*If **NO**, check the deficient step(s):*

____ *a. Discard the urine collected (if any)*

____*b. Immediately notify the agency's designated representative of the refusal (e.g., by telephone, secure fax machine, e-mail)*

____ *c. Document the refusal to test with appropriate comments, signature, and date in the Remarks line of Step 2 of the Federal CCF*

____ *d. Send all copies of the Federal CCF to the federal agency's designated representative*

Comment: When reporting a refusal to test, the collector must discard all urine collected (if any). The collector must immediately notify the federal agency's designated representative by a means (e.g., by telephone, secure fax machine, e-mail) that ensures immediate receipt of the refusal notification. The collector must document the refusal to

test with appropriate comments, signature, and date in the Remarks line of Step 2 of the Federal CCF, and send all copies of the Federal CCF to the federal agency's designated representative.

Reference: HHS Mandatory Guidelines (subpart A Section 1.8.b –subpart H section 8.13)

Collector Errors

Question D-18. *When the collector realizes that an incorrect or expired Federal CCF is used prior to packaging the specimen bottles, does the collector document on the form that the specimen is a federal agency specimen and provide the reason for the incorrect form? (YES/NO)*

Comment: If an incorrect or expired Federal CCF is used, the collector must document on the form that the specimen is a federal agency specimen and provide the reason for the incorrect form. Based on the information provided by the collector, the testing facility will handle and test the specimen as a federal agency specimen.

Note: The collector may document the reason for using the incorrect form on an MFR attached to the form.

Reference: HHS Mandatory Guidelines (subpart E – section 6.2.b)

Question D-19*. Does the collector provide a memorandum for the record (MFR) when requested by the HHS-certified test facility (i.e., laboratory, IITF) or MRO? (YES/NO)*

Comment: The collector must take **immediate** steps to provide an MFR to the testing facility (i.e., IITF or laboratory), or MRO when notified of an error. The MFR must be sent to the requester within one business day.

There are three categories of collector errors:

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

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

Reference: HHS Mandatory Guidelines (subpart E – section 6.2.c) and HHS Collection Handbook

Section Evaluation

Question D-20. *For the Collection Problems Section:*

____ *Serious deficiencies were identified (0 points)*
____ *Deficiencies were identified (1 point)*
____ *No deficiencies were identified (2 points)*

Note: This page is included to facilitate the evaluation of compliance with program requirements. The inspector/reviewer should explain the potential problem or identified non-compliance associated with the checklist questions in this section. Serious deficiencies require immediate corrective action by the collection site to maintain the integrity of the collection process, to maintain the security and integrity of the specimens collected, and to ensure the privacy of the donors.

Describe basis for the above selection:

Section E. Collection Site Records

Question E-1. *Are collection site records including Copy 3 of the Federal Custody and Control Form (Federal CCF) stored for a minimum of two years? (YES/NO)*

Comment: The collector or collector's employer must maintain collection site records (e.g., Copy 3 of the Federal CCF) for a minimum of two years.

Reference: HHS Mandatory Guidelines (subpart E - section 5.4)

Question E-2. *Are collection site records stored and disposed of in a manner that ensures donor confidentiality? (YES/NO)*

Comment: The collection site must have the ability to store records securely. Records must be stored and disposed of in a manner that ensures donor confidentiality.

Reference: HHS Mandatory Guidelines (subpart E - section 5.3) and HHS Collection Handbook

Question E-3. *Have collectors properly completed the Federal CCF? (YES/NO)*

Comment: The collector is responsible for completing Steps 1, 2, and 4 on the Federal CCF.

Reference: HHS Collection Handbook

Question E-4. *Are edits to the Federal CCF properly made, initialed and dated? (YES/NO)*

Comment: 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 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 single line through the erroneous information, leaving the 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, 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.

Reference: HHS Collection Handbook

Section Evaluation

E-5. ***For the Collection Site Records Section:***

____ *Serious deficiencies were identified (0 points)*
____ *Deficiencies were identified (1 point)*
____ *No deficiencies were identified (2 points)*

Note: This page is included to facilitate the evaluation of compliance with program requirements. The inspector/reviewer should explain the potential problem or identified non-compliance associated with the checklist questions in this section. Serious deficiencies require immediate corrective action by the collection site to maintain the integrity of the collection process, to maintain the security and integrity of the specimens collected, and to ensure the privacy of the donors.

Describe basis for the above selection:

Collection Site Evaluation Form

Overall Section Summary			
Checklist Sections	Serious Deficiencies Identified (0)	Deficiencies Identified (1)	No Deficiencies Identified (2)
A. Collection Site			
B. Personnel			
C. Specimen Collection Procedures			
D. Collection Problems			
E. Collection Site Records			

Overall Summary of Serious Deficiencies (List Sections)		
	Serious Deficiencies were identified	***No Serious Deficiencies were identified***
Inspector / Collection Site Reviewer		
Federal Agency/ Designee		

Inspection Outcome			
Rating (out of 10)		Acceptable: *rating ≥ 5 and no more than one section with serious deficiencies*	
Inspector / Collection Site Reviewer	___/10	Unacceptable: *rating < 5 or more than one section with serious deficiencies*	
Federal Agency/ Designee	___/10	**Outcome:**	

Additional Comments: _____

_____

_____

Acceptable Outcome for Inspection: Yes _____ No _____

Self-Evaluation by: _____ Date:_____

Onsite Inspection by: _____ Date:_____

Approved by: _____ Date:_____

Position/Title: _____

Attachment 1: Mandatory Guidelines Subparts D-H

Subpart D--Collectors

4.1 Who may collect a specimen?
4.2 Who may not collect a specimen?
4.3 What are the requirements to be a collector?
4.4 What are the requirements to be an observer for a direct observed collection?
4.5 What are the requirements to be a trainer for collectors?
4.6 What must a federal agency do before an individual is permitted to collect a specimen?

Subpart E--Collection Sites

5.1 Where can a collection for a drug test take place?
5.2 What are the requirements for a collection site?
5.3 Where must collection site records be stored?
5.4 How long must collection site records be stored?
5.5 How does the collector ensure the security and integrity of a specimen at the collection site?
5.6 What are the privacy requirements when collecting a urine specimen?

Subpart F--Federal Drug Testing Custody and Control Form

6.1 What federal form is used to document custody and control?
6.2 What happens if the correct OMB-approved Federal CCF is not available or is not used?

Subpart G—Urine Specimen Collection Containers and Bottles

7.1 What is used to collect a urine specimen?
7.2 What are the requirements for a urine collection container and specimen bottles?
7.3 What are minimum performance requirements for a urine collection container and specimen bottles?

Subpart H—Urine Specimen Collection Procedure

8.1 What privacy must the donor be given when providing a specimen?
8.2 What must the collector ensure at the collection site before starting a urine specimen collection?
8.3 What are the preliminary steps in the urine specimen collection procedure?
8.4 What steps does the collector take in the collection procedure before the donor provides a urine specimen?
8.5 What steps does the collector take during and after the urine specimen collection procedure?
8.6 What procedure is used when the donor states that they are unable to provide a specimen?
8.7 If the donor is unable to provide a urine specimen, may another specimen type be collected for testing?
8.8 How does the collector prepare the specimens?

Subpart D - Collectors

Section 4.1 Who may collect a specimen?

(a) A collector who has been trained to collect urine specimens in accordance with these Guidelines.

(b) The immediate supervisor of a federal employee donor may only collect that donor's specimen when no other collector is available. The supervisor must be a trained collector.

(c) The hiring official of a federal agency applicant may only collect that federal agency applicant's specimen when no other collector is available. The hiring official must be a trained collector.

Section 4.2 Who may not collect a specimen?

(a) A federal agency employee who is in a testing designated position and subject to the federal agency drug testing rules must not be a collector for co-workers in the same testing pool or who work together with that employee on a daily basis.

(b) A federal agency applicant or employee must not collect their own drug testing specimen.

(c) An employee working for an HHS-certified laboratory or IITF must not act as a collector if the employee could link the identity of the donor to the donor's drug test result.

(d) To avoid a potential conflict of interest, a collector must not be related to the employee (e.g., spouse, ex-spouse, relative) or a close personal friend (e.g., fiancée).

Section 4.3 What are the requirements to be a collector?

(a) An individual may serve as a collector if they fulfill the following conditions:

(1) Is knowledgeable about the collection procedure described in these Guidelines;

(2) Is knowledgeable about any guidance provided by the federal agency's Drug-Free Workplace Program and additional information provided by the Secretary relating to these Guidelines;

(3) Is trained and qualified to collect a urine specimen. Training must include the following:

(i) All steps necessary to complete a urine collection;

(ii) Completion and distribution of the Federal CCF;

(iii) Problem collections;

(iv) Fatal flaws, correctable flaws, and how to correct problems in collections; and

(v) The collector's responsibility for maintaining 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.

(4) Has demonstrated proficiency in collections by completing five consecutive error-free mock collections.

(i) The five mock collections must include one uneventful collection 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 seal.

(ii) A 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.

(b) A trained collector must complete refresher training at least every five years that includes the requirements in paragraph (a) of this section.

(c) The collector must maintain the documentation of their training and provide that documentation to a federal agency when requested.

(d) An individual may not collect specimens for a federal agency until the individual's training as a collector has been properly documented.

Section 4.4 What are the requirements to be an observer for a direct observed collection?

(a) An individual may serve as an observer for a direct observed collection when the individual has satisfied the requirements:

(1) Is knowledgeable about the direct observed collection procedure described in Section 8.9 of these Guidelines;

(2) Is knowledgeable about any guidance provided by the federal agency's Drug-Free Workplace Program or additional information provided by the Secretary relating to the direct observed collection procedure described in these Guidelines;

(3) Has received training on the following subjects:

(i) All steps necessary to perform a direct observed collection; and

(ii) The observer's responsibility for maintaining the integrity of the collection process, ensuring the privacy of individuals being tested, ensuring that the observation is done in a professional manner that minimizes the discomfort to the employee so observed, ensuring the security of the specimen by maintaining visual contact with the collection container until it is delivered to the collector, and avoiding conduct or statements that could be viewed as offensive or inappropriate.

(b) The gender of the observer must be the same as the donor's gender, which is determined by the donor's gender identity. The observer selection process is described in Section 8.10(b).

(c) The observer is not required to be a trained collector.

Section 4.5 What are the requirements to be a trainer for collectors?

(a) Individuals are considered qualified trainers for collectors and may train others to collect urine specimens when they have completed the following:

(1) Qualified as a trained collector and regularly conducted urine drug test collections for a period of at least one year or

(2) Completed a "train the trainer" course given by an organization (e.g., manufacturer, private entity, contractor, federal agency).

(b) A qualified trainer for collectors must complete refresher training at least every five years in accordance with the collector requirements in Section 4.3(a).

(c) A qualified trainer for collectors must maintain the documentation of the

trainer's training and provide that documentation to a federal agency when requested.

Section 4.6 What must a federal agency do before a collector is permitted to collect a specimen?

A federal agency must ensure the following:

(a) The collector has satisfied the requirements described in Section 4.3;
(b) The collector, who may be self-employed, or an organization (e.g., third party administrator that provides a collection service, collector training company, federal agency that employs its own collectors) maintains a copy of the training record(s); and
(c) The collector has been provided the name and telephone number of the federal agency representative.

Subpart E - Collection Sites

Section 5.1 Where can a collection for a drug test take place?

(a) A collection site may be a permanent or temporary facility located either at the work site or at a remote site.
(b) In the event that an agency-designated collection site is not accessible and there is an immediate requirement to collect a urine specimen (e.g., an accident investigation), a public restroom may be used for the collection, using the procedures for a monitored collection described in Section 8.12.

Section 5.2 What are the requirements for a collection site?

The facility used as a collection site must have the following:
(a) Provisions to ensure donor privacy during the collection (as described in Section 8.1);
(b) A suitable and clean surface area that is not accessible to the donor for handling the specimens and completing the required paperwork;
(c) A secure temporary storage area to maintain specimens until the specimen is transferred to an HHS-certified laboratory or IITF;
(d) A restricted access area where only authorized personnel may be present during the collection;
(e) A restricted access area for the storage of collection supplies;
(f) The ability to store records securely; and
(g) The ability to restrict the donor access to potential diluents in accordance with Section 8.2.

Section 5.3 Where must collection site records be stored?

Collection site records must be stored at a secure site designated by the collector or the collector's employer.

Section 5.4 How long must collection site records be stored?

Collection site records (e.g., collector copies of the OMB-approved Federal CCF) must be stored securely for a minimum of 2 years. The collection site may convert hardcopy records to electronic records for storage and discard the hardcopy records

after 6 months.

Section 5.5 How does the collector ensure the security and integrity of a specimen at the collection site?

(a) A collector must do the following to maintain the security and integrity of a specimen:
(1) Not allow unauthorized personnel to enter the collection area during the collection procedure;
(2) Perform only one donor collection at a time;
(3) Restrict access to collection supplies before, during and after collection;
(4) Ensure that only the collector and the donor are allowed to handle the unsealed specimen;
(5) Ensure the chain of custody process is maintained and documented throughout the entire collection, storage, and transport procedures;
(6) Ensure that the Federal CCF is completed and distributed as required; and
(7) Ensure that specimens transported to an HHS-certified laboratory or IITF are sealed and placed in transport containers designed to minimize the possibility of damage during shipment (e.g., specimen boxes, padded mailers, or other suitable shipping container), and those containers are securely sealed to eliminate the possibility of undetected tampering;
(b) Couriers, express carriers, and postal service personnel are not required to document chain of custody since specimens are sealed in packages that would indicate tampering during transit to the HHS-certified laboratory or IITF.

Section 5.6 What are the privacy requirements when collecting a urine specimen?

Collections must be performed at a site that provides reasonable privacy (as described in Section 8.1).

Subpart F - Federal Drug Testing Custody and Control Form

Section 6.1 What federal form is used to document custody and control?

The OMB-approved Federal CCF must be used to document custody and control of each specimen at the collection site.

Section 6.2 What happens if the correct OMB-approved Federal CCF is not available or is not used?

(a) The use of a non-federal CCF or an expired Federal CCF is not, by itself, a reason for the HHS-certified laboratory or IITF to automatically reject the specimen for testing or for the MRO to cancel the test.
(b) If the collector does not use the correct 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. Based on the information provided by the collector, the HHS-certified laboratory or IITF must handle and test the specimen as a federal agency specimen.
(c) If the HHS-certified laboratory, HHS-certified IITF, or MRO discovers that the collector used an incorrect form, the laboratory, IITF, or MRO must obtain a memorandum for the record from the collector describing the reason the incorrect form

was used. If a memorandum for the record cannot be obtained, the laboratory or IITF reports a rejected for testing result to the MRO and the MRO cancels the test. The HHS-certified laboratory or IITF must wait at least 5 business days while attempting to obtain the memorandum before reporting a rejected for testing result to the MRO.

Subpart G – Urine Specimen Collection Containers and Bottles

Section 7.1 What is used to collect a urine specimen?

A single-use collection container with a means (i.e., thermometer) to measure urine temperature and two specimen bottles must be used.

Section 7.2 What are the requirements for a urine collection container and specimen bottles?

(a) The collection container, the thermometer, and the specimen bottles must not substantially affect the composition of drugs and/or metabolites in the urine specimen.
(b) The two specimen bottles must be sealable and non-leaking, and must maintain the integrity of the specimen during storage and transport so that the specimen contained therein can be tested in an HHS-certified laboratory or IITF for the presence of drugs or their metabolites.
(c) The two specimen bottles must be sufficiently transparent to enable an objective assessment of specimen appearance and identification of abnormal physical characteristics without opening the bottle.

Section 7.3 What are the minimum performance requirements for a urine collection container and specimen bottles?

(a) The collection container must be capable of holding at least 55 mL and have a volume marking clearly noting a level of 45 mL.
(b) One of the two specimen bottles must be capable of holding at least 35 mL and the other at least 20 mL, and each must have a volume marking clearly noting the appropriate level (30 mL for the primary specimen and 15 mL for the split specimen).
(c) The thermometer may be affixed to or built into the collection container and must provide graduated temperature readings from 32–38 °C/90–100 °F. Alternatively, the collector may use another technology to measure specimen temperature (e.g., thermal radiation scanning), providing the thermometer does not come into contact with the specimen.

Subpart H - Urine Specimen Collection Procedure

Section 8.1 What privacy must the donor be given when providing a urine specimen?

The following privacy requirements apply when a donor is providing a urine specimen:
(a) Only authorized personnel and the donor may be present in the restricted access area where the collection takes place.
(b) The collector is not required to be the same gender as the donor. The gender of the observer for purposes of a direct observed collection (i.e., as described in Section 8.10) must be the same as the donor's gender, which is determined by the donor's gender identity. The gender of the monitor for a monitored collection (i.e., as described

in Section 8.12) must be the same as the donor's gender, unless the monitor is a medical professional (e.g., nurse, doctor, physician's assistant, technologist, or technician licensed or certified to practice in the jurisdiction in which the collection takes place).

(c) The collector must give the donor visual privacy while providing the specimen. The donor is allowed to provide a urine specimen in an enclosed stall within a multi-stall restroom or in a single person restroom during a monitored collection.

Section 8.2 What must the collector ensure at the collection site before starting a urine specimen collection?

The collector must deter the dilution or substitution of a specimen at the collection site by:

(a) Placing a toilet bluing agent in a toilet bowl or toilet tank, so the reservoir of water in the toilet bowl always remains blue. If no bluing agent is available or if the toilet has an automatic flushing system, the collector shall turn the water supply off to the toilet and flush the toilet to remove the water in the toilet when possible.

(b) Secure other sources of water (e.g., shower or sink) in the enclosure where urination occurs. If the enclosure has a source of water that cannot be disabled or secured, a monitored collection must be conducted in accordance with Section 8.11.

Section 8.3 What are the preliminary steps in the urine specimen collection procedure?

The collector must take the following steps before beginning a urine specimen collection:

(a) If a donor fails to arrive at the collection site at the assigned time, the collector must follow the federal agency policy or contact the federal agency representative to obtain guidance on action to be taken.

(b) When the donor arrives at the collection site, the collector should begin the collection procedure without undue delay. For example, the collection should not be delayed because the donor states that they are unable to urinate or an authorized employer or employer representative is late in arriving.

(c) The collector requests the donor to present photo identification (e.g., driver's license; employee badge issued by the employer; an alternative photo identification issued by a federal, state, or local government agency). If the donor does not have proper photo identification, the collector shall contact the supervisor of the donor or the federal agency representative who can positively identify the donor. If the donor's identity cannot be established, the collector must not proceed with the collection.

(d) The collector must provide identification (e.g., employee badge, employee list) if requested by the donor.

(e) The collector explains the basic collection procedure to the donor.

(f) The collector informs the donor that the instructions for completing the Federal Custody and Control Form are located on the back of the Federal CCF or available upon request.

(g) The collector answers any reasonable and appropriate questions the donor may have regarding the collection procedure.

(h) The collector asks the donor to remove any unnecessary outer garments (e.g., coat, jacket) that might conceal items or substances that could be used to adulterate or substitute the urine specimen:

(1) The collector must ensure that all personal belongings (e.g., purse or briefcase) remain with the outer garments; the donor may retain the donor's wallet.

(2) The collector asks the donor to empty the donor's pockets and display the contents to ensure no items are present that could be used to adulterate or substitute the specimen.

(3) If no items are present that can be used to adulterate or substitute the specimen, the donor can place the items back into the donor's pockets and continue the collection procedure.

(4) 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. The collector must stop the collection and report the refusal to test as described in Section 8.13. If the item appears to be inadvertently brought to the collection site, the collector must secure the item and continue the normal collection procedure.

(5) If the donor refuses to show the collector the items in the donor's pockets, this is considered a refusal to test. The collector must stop the collection and report the refusal to test as described in Section 8.13.

(i) The collector shall instruct the donor to wash and dry the donor's hands prior to urination. After washing the donor's hands, the donor must remain in the presence of the collector and must not have access to any water fountain, faucet, soap dispenser, cleaning agent, or any other materials which could be used to adulterate or substitute the specimen.

(1) If the donor refuses to wash the donor's hands when instructed by the collector, this is considered a "refusal to test." The collector must stop the collection and report the refusal to test as described in Section 8.13.

Section 8.4 What steps does the collector take in the collection procedure before the donor provides a urine specimen?

(a) The collector will provide or the donor may select a specimen collection container that is clean, unused, wrapped/sealed in original packaging and compliant with Subpart G. The specimen collection container will be opened in view of the donor.

(b)The collector instructs the donor to provide the specimen in the privacy of a stall or otherwise partitioned area that allows for individual privacy. The collector directs the donor to provide a specimen of at least 45 mL, to not flush the toilet, and to return with the specimen as soon as the donor has completed the void.

(1) Except in the case of a direct observed collection (i.e., as described in Section 8.10) or a monitored collection (i.e., as described in Section 8.12), neither the collector nor anyone else may go into the room with the donor.

(2) The collector may set a reasonable time limit for specimen collection.

(c) The collector notes any unusual behavior or appearance of the donor on the Federal CCF. If the collector detects 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), the collector must report a refusal to test in accordance with Section 8.13.

Section 8.5 What steps does the collector take during and after the urine specimen collection procedure?

Integrity and Identity of the Specimen. The collector must take the following steps during and after the donor provides the urine specimen:

(a) The collector must inform the donor that, once the collection procedure has begun, the donor must remain at the collection site (i.e., in an area designated by the

collector) until the collection is complete. This includes the wait period (i.e., up to 3 hours) if needed to provide a sufficient specimen as described in step (f)(2) below and in Section 8.6.

(b) After providing the specimen, the donor gives the specimen collection container to the collector. Both the donor and the collector must keep the specimen container in view at all times until the collector seals the specimen bottles as described in Section 8.8.

(c) After the donor has given the specimen to the collector, whenever practical, the donor shall be allowed to wash the donor's hands and the donor may flush the toilet.

(d) The collector must measure the temperature of the specimen within 4 minutes of receiving the specimen from the donor. The collector records on the Federal CCF whether or not the temperature is in the acceptable range of 32°-38°C/90°-100°F.

(1) The temperature measuring device must accurately reflect the temperature of the specimen and not contaminate the specimen.

(2) If the temperature of the specimen is outside the range of 32°-38°C/90°-100°F, that is a reason to believe that the donor may have adulterated or substituted the specimen. Another specimen must be collected under direct observation in accordance with Section 8.9. The collector must forward both specimens (i.e., from the first and second collections) to an HHS-certified laboratory for testing and record a comment on the Federal CCF for each specimen.

(e) The collector must inspect the specimen to determine if there is any sign indicating that the specimen may not be a valid urine specimen (e.g., unusual color, presence of foreign objects or material, unusual odor).

(1) The collector notes any unusual finding on the Federal CCF. A specimen suspected of not being a valid urine specimen must be forwarded to an HHS-certified laboratory for testing.

(2) When there is any reason to believe that a donor may have adulterated or substituted the specimen, another specimen must be obtained as soon as possible under direct observation in accordance with Section 8.10. The collector must forward both specimens (i.e., from the first and second collections) to an HHS-certified laboratory for testing and record a comment on the Federal CCF for each specimen.

(f) The collector must determine the volume of urine in the specimen container. The collector must never combine urine collected from separate voids to create a specimen.

(1) If the volume is at least 45 mL, the collector will proceed with steps described in Section 8.8.

(2) If the volume is less than 45 mL, the collector discards the specimen and immediately collects a second specimen using the same procedures as for the first specimen (including steps in paragraphs c and d of this section).

(i) The collector may give the donor a reasonable amount of liquid to drink for this purpose (e.g., an 8 ounce glass of water every 30 minutes, but not to exceed a maximum of 40 ounces over a period of 3 hours or until the donor has provided a sufficient urine specimen). However, the donor is not required to drink any fluids during this waiting time.

(ii) If the donor provides a sufficient urine specimen (i.e., at least 45 mL), the collector proceeds with steps described in Section 8.8.

(iii) If the employee has not provided a sufficient specimen (i.e., at least 45 mL) within three hours of the first unsuccessful attempt to provide the specimen, the collector records the reason for not collecting a urine specimen on the Federal CCF, notifies the federal agency's designated representative for authorization of an alternate specimen to be collected, and sends the appropriate copies of the Federal CCF to the

MRO and to the federal agency's designated representative. 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. If an alternate specimen is authorized, the collector may begin the collection procedure for the alternate specimen (see Section 8.7) in accordance with the Mandatory Guidelines for Federal Workplace Drug Testing Programs using the alternative specimen.

(g) If the donor fails to remain present through the completion of the collection, declines to have a direct observed collection as required in steps (d)(2) or (e)(2) above, refuses to provide a second specimen as required in step (f)(2) above, or refuses to provide an alternate specimen as authorized in step (f)(2)(iii) above, the collector stops the collection and reports the refusal to test in accordance with Section 8.13.

Section 8.6 What procedure is used when the donor states that they are unable to provide a urine specimen?

(a) If the donor states that they are unable to provide a urine specimen during the collection process, the collector requests that the donor enter the restroom (stall) and attempt to provide a urine specimen.

(b) The donor demonstrates their inability to provide a specimen when he or she comes out of the stall with an empty collection container.

(1) If the donor states that they could provide a specimen after drinking some fluids, the collector gives the donor a reasonable amount of liquid to drink for this purpose (e.g., an 8 ounce glass of water every 30 minutes, but not to exceed a maximum of 40 ounces over a period of 3 hours or until the donor has provided a sufficient urine specimen). If the donor simply needs more time before attempting to provide a urine specimen, the donor is not required to drink any fluids during the 3 hour wait time.

(2) If the donor states that they are unable to provide a urine specimen, the collector records the reason for not collecting a urine specimen on the Federal CCF, notifies the federal agency's designated representative for authorization of an alternate specimen to be collected, and sends the appropriate copies of the Federal CCF to the MRO and to the federal agency's designated representative. 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. If an alternate specimen is authorized, the collector may begin the collection procedure for the alternate specimen (see Section 8.7) in accordance with the Mandatory Guidelines for Federal Workplace Drug Testing Programs using the alternative specimen.

Section 8.7 If the donor is unable to provide a urine specimen, may another specimen type be collected for testing?

Yes, if the alternate specimen type is authorized by Mandatory Guidelines for Federal Workplace Drug Testing Programs and specifically authorized by the federal agency.

Section 8.8 How does the collector prepare the urine specimens?

(a) All federal agency collections are to be split specimen collections.

(b) The collector, in the presence of the donor, pours the urine from the collection

container into two specimen bottles to be labeled “A” and “B”. The collector pours at least 30 mL of urine into Bottle A and at least 15 mL into Bottle B, and caps each bottle.

(c) In the presence of the donor, the collector places a tamper-evident label/seal from the Federal CCF over each specimen bottle cap. The collector records the date of the collection on the tamper-evident labels/seals.

(d) The collector instructs the donor to initial the tamper-evident labels/seals on each specimen bottle. If the donor refuses to initial the labels/seals, the collector notes the refusal on the Federal CCF and continues with the collection process.

(e) The collector must ensure that all the information required on the Federal CCF is provided.

(f) The collector asks the donor to read and sign a statement on the Federal CCF certifying that the specimens identified were collected from the donor. If the donor refuses to sign the certification statement, the collector notes the refusal on the Federal CCF and continues with the collection process.

(g) The collector signs and prints their name on the Federal CCF, completes the Federal CCF, and distributes the copies of the Federal CCF as required.

(h) The collector seals the specimens (Bottle A and Bottle B) in a package and, within 24 hours or during the next business day, sends them to the HHS-certified laboratory or IITF that will be testing the Bottle A urine specimen.

(i) If the specimen and Federal CCF are not immediately transported to an HHS-certified laboratory or IITF, they must remain under direct control of the collector or be appropriately secured under proper specimen storage conditions until transported.

(j) The collector must discard any urine left over in the collection container after both specimen bottles have been appropriately filled and sealed. There is one exception to this requirement: the collector may use excess urine to conduct clinical tests (e.g., protein, glucose) if the collection was conducted in conjunction with a physical examination required by federal agency regulation. Neither the collector nor anyone else may conduct further testing (such as specimen validity testing) on the excess urine.

Section 8.9 When is a direct observed collection conducted?

A direct observed collection procedure must be conducted when:

(a) The agency has authorized a direct observed collection because:

(1) The donor’s previous drug test result was reported by an MRO as positive, adulterated, or substituted; or

(2) The HHS-certified laboratory reports to the MRO that a specimen is invalid, and the MRO reported to the agency that there was not a legitimate medical explanation for the result; or

(3) The MRO reported to the agency that the primary bottle (A) specimen was positive, adulterated, or substituted result had to be cancelled because the test of the split specimen could not be tested and /or the split specimen bottle (B) failed to reconfirm; or

(b) At the collection site, an immediate collection of a second urine specimen is required because:

(1) The temperature of the specimen collected during a routine collection is outside the acceptable temperature range; or

(2) The collector suspects that the donor has tampered with the specimen during a routine collection (e.g., abnormal physical characteristic such as unusual color and/or odor, and/or excessive foaming when shaken).

(c) The collector must contact a collection site supervisor to review and concur in

advance with any decision by the collector to obtain a specimen under direct observation.

(d) If the donor declines to have a direct observed collection, the collector reports a refusal to test (i.e., as described in Section 8.13).

Section 8.10 How is a direct observed collection conducted?

(a) A direct observed collection procedure is the same as that for a routine collection, except an observer watches the donor urinate into the collection container. The observer's gender must be the same as the donor's gender, which is determined by the donor's gender identity, with no exception to this requirement.

(b) Before an observer is selected, 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 (as defined in Section 1.5). The collector then selects the observer to conduct the observation:

(i) The collector asks the donor to identify the donor's gender on the Federal CCF and initial it.

(ii) The donor will then be provided an observer whose gender matches the donor's gender.

(iii) The collector documents the observer's name and gender on the Federal CCF.

(c) If there is no collector available of the same gender as the donor's gender, the collector or collection site supervisor shall select an observer trained in direct observed specimen collection as described in Section 4.4. The observer may be an individual that is not a trained collector.

(d) At the point in a routine collection where the donor enters the restroom with the collection container, a direct observed collection includes the following additional steps:

(1) The observer enters the restroom with the donor;

(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);

(3) The observer must not 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:

(i) If the same person serves as the observer and collector, that person may receive the collection container from the donor while they are both in the restroom;

(ii) If the observer is not serving as the collector, the donor and observer leave the restroom and the donor hands the collection container directly to the collector. The observer must maintain visual contact of the collection container until the donor hands the container to the collector.

(5) The collector checks the box for an observed collection on the Federal CCF and writes the name of the observer and the reason for an observed collection on the Federal CCF; and

(6) The collector then continues with the routine collection procedure in Section 8.3.

Section 8.11 When is a monitored collection conducted?

(a) In the event that an agency-designated collection site is not available and there is an immediate requirement to collect a specimen (e.g., an accident investigation), a public restroom may be used for the collection, using the procedures

for a monitored collection described in Section 8.12.

(b) If the enclosure used by the donor to provide a specimen has a source of water that cannot be disabled or secured, a monitored collection must be conducted.

(c) If the donor declines to permit a collection to be monitored when required, the collector reports a refusal to test (i.e., as described in Section 8.13).

Section 8.12 How is a monitored collection conducted?

A monitored collection is the same as that for a routine collection, except that a monitor accompanies the donor into the restroom to check for signs that the donor may be tampering with the specimen. The monitor remains in the restroom, but outside the stall, while the donor is providing the specimen. A person of the same gender as the donor shall serve as the monitor, unless the monitor is a medical professional (e.g., nurse, doctor, physician's assistant, technologist, or technician licensed or certified to practice in the jurisdiction in which the collection takes place). The same procedures used for selecting an observer of the appropriate gender in Section 8.10(b) must be used to select the monitor for the purposes of Section 8.12, unless the monitor is a medical professional as described above. The monitor may be an individual other than the collector and need not be a qualified collector.

(a) The collector secures the restroom being used for the monitored collection so that no one except the employee and the monitor can enter the restroom until after the collection has been completed.

(b) The monitor enters the restroom with the donor.

(c) The monitor must not watch the employee urinate into the collection container. If the monitor hears sounds or makes other observations indicating an attempt by the donor to tamper with a specimen, there must be an additional collection under direct observation in accordance with Section 8.9.

(d) The monitor must not touch or handle the collection container unless the monitor is also the collector.

(e) After the donor has completed urinating into the collection container:

(1) If the same person serves as the monitor and collector, that person may receive the collection container from the donor while they are both in the restroom;

(2) If the monitor is not serving as the collector, the donor and monitor leave the restroom and the donor hands the collection container directly to the collector. The monitor must ensure that the employee takes the collection container directly to the collector as soon as the employee has exited the enclosure.

(f) If the monitor is not serving as the collector, the collector writes the name of the monitor on the Federal CCF.

(g) The collector then continues with the routine collection procedure in Section 8.3.

Section 8.13 How does the collector report a donor’s refusal to test?

If there is a refusal to test as defined in Section 1.7, the collector stops the collection, discards any urine collected and reports the refusal to test by:

(a) Notifying the federal agency by means (e.g., telephone, e-mail, or secure fax) that ensures that the notification is immediately received,

(b) Documenting the refusal to test on the Federal CCF, and

(c) Sending all copies of the Federal CCF to the federal agency’s designated representative.

Section 8.14 What are a federal agency's responsibilities for a collection site?

(a) A federal agency must ensure that collectors and collection sites satisfy all requirements in subparts D, E, F, G, and H.

(b) A federal agency (or only one federal agency when several agencies are using the same collection site) must inspect 5 percent or up to a maximum of 50 collection sites each year, selected randomly from those sites used to collect agency specimens (e.g., virtual, onsite, or self-evaluation).

(c) A federal agency must investigate reported collection site deficiencies (e.g., specimens reported "rejected for testing" by an HHS-certified laboratory or IITF) and take appropriate action which may include a collection site self-assessment (i.e., using the Collection Site Checklist for the Collection of Urine Specimens for Federal Agency Workplace Drug Testing Programs) or an inspection of the collection site. The inspections of these additional collection sites may be included in the 5 percent or maximum of 50 collection sites inspected annually.